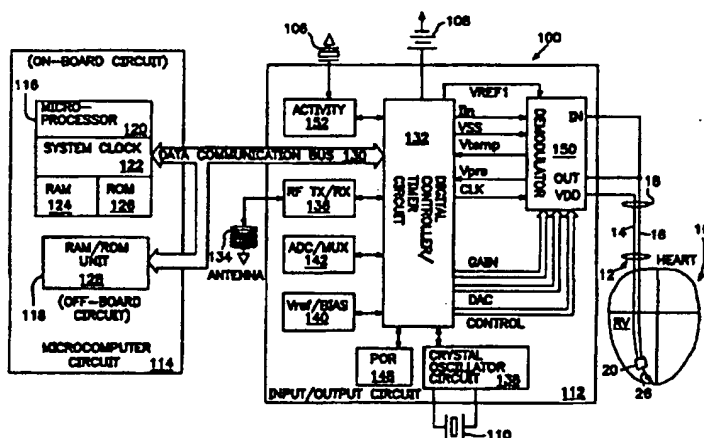




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | |
|---|--|--|--|
| (51) International Patent Classification 6 : A61B 5/00 | | A1 | (11) International Publication Number: WO 96/26670 |
| | | | (43) International Publication Date: 6 September 1996 (06.09.96) |
| (21) International Application Number: PCT/US96/00975 | | (81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). | |
| (22) International Filing Date: 24 January 1996 (24.01.96) | | | |
| (30) Priority Data: 08/394,870 27 February 1995 (27.02.95) US | | Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. | |
| (71) Applicant: MEDTRONIC, INC. [US/US]; 7000 Central Avenue Northeast, Minneapolis, MN 55432 (US). | | | |
| (72) Inventors: HALPERIN, Louis, E.; 1524 Goodrich Avenue, St. Paul, MN 55105 (US). MIESEL, Keith, A.; 896 Ashland Avenue, St. Paul, MN 55104 (US). UFFORD, Keith, A.; 11337 Lekoday Lane, Chisago City, MN 55013 (US). SVENSK, James, R.; 948 119th Lane Northwest, Coon Rapids, MN 55448 (US). PATRICK, Timothy; 117 11th Avenue North, St. Paul, MN 55075 (US). HASSLER, Beth, Anne, H.; 1512 Park Street #8, White Bear Lake, MN 55110 (US). VARRICHIO, Anthony, J.; 1 Hemlock Lane, Flanders, NJ 07836 (US). | | | |
| (74) Agents: ATLASS, Michael, B. et al.; Medtronic, Inc., 7000 Central Avenue Northeast, MS301, Minneapolis, MN 55432 (US). | | | |

(54) Title: IMPLANTABLE CAPACITIVE ABSOLUTE PRESSURE AND TEMPERATURE SENSOR



(57) Abstract

An endocardial lead (12) for implantation in a right heart chamber (RV) for responding to blood pressure and temperature and providing modulated pressure and temperature related signals to an implanted or external hemodynamic monitor (100) and/or cardiac pacemaker or pacemaker/cardioverter/defibrillator. The lead (12) has a sensor module (20) formed in its distal end and is coupled to a monitor (100) that powers a sensor circuit in the sensor module. The sensor module is formed with a pickoff capacitor (Cp) that changes capacitance with pressure changes and a reference capacitor (Cp) that is relatively insensitive to pressure changes. The sensor circuit provides charge current that changes with temperature variation at the implant site, alternately charges and discharges the two capacitors, and provides timing pulses having distinguishable parameters at the end of each charge cycle that are transmitted to a demodulator (150). The demodulator (150) detects and synchronizes the timing pulses and derives pressure and temperature analog voltage values representative of the intervals between the timing pulses which are digitized and stored in the monitor. The monitor may also be coupled with other sensors (106, 152) for measuring and storing related patient body parameters, e.g. blood gas, ECG, and patient activity.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | |
|----|--------------------------|----|--|----|--------------------------|
| AM | Armenia | GB | United Kingdom | MW | Malawi |
| AT | Austria | GE | Georgia | MX | Mexico |
| AU | Australia | GN | Guinea | NE | Niger |
| BB | Barbados | GR | Greece | NL | Netherlands |
| BE | Belgium | HU | Hungary | NO | Norway |
| BF | Burkina Faso | IE | Ireland | NZ | New Zealand |
| BG | Bulgaria | IT | Italy | PL | Poland |
| BJ | Benin | JP | Japan | PT | Portugal |
| BR | Brazil | KE | Kenya | RO | Romania |
| BY | Belarus | KG | Kyrgyzstan | RU | Russian Federation |
| CA | Canada | KP | Democratic People's Republic of Korea | SD | Sudan |
| CF | Central African Republic | KR | Republic of Korea | SE | Sweden |
| CG | Congo | KZ | Kazakhstan | SG | Singapore |
| CH | Switzerland | LI | Liechtenstein | SI | Slovenia |
| CI | Côte d'Ivoire | LK | Sri Lanka | SK | Slovakia |
| CM | Cameroon | LR | Liberia | SN | Senegal |
| CN | China | LT | Lithuania | SZ | Swaziland |
| CS | Czechoslovakia | LU | Luxembourg | TD | Chad |
| CZ | Czech Republic | LV | Latvia | TG | Togo |
| DE | Germany | MC | Monaco | TJ | Tajikistan |
| DK | Denmark | MD | Republic of Moldova | TT | Trinidad and Tobago |
| EE | Estonia | MG | Madagascar | UA | Ukraine |
| ES | Spain | ML | Mali | UG | Uganda |
| FI | Finland | MN | Mongolia | US | United States of America |
| FR | France | MR | Mauritania | UZ | Uzbekistan |
| GA | Gabon | | | VN | Viet Nam |

IMPLANTABLE CAPACITIVE ABSOLUTE PRESSURE AND TEMPERATURE SENSOR

5

BACKGROUND OF THE INVENTION

Field of the Invention. The present invention relates to a body implantable pressure sensor, particularly attached to an endocardial lead for implantation in a right heart chamber, for responding to blood and atmospheric pressure and blood temperature and providing modulated pressure and temperature related signals to an implanted or
10 external hemodynamic monitor and/or cardiac pacemaker or
pacemaker/cardioverter/defibrillator.

Description of the Background Art. Efforts have been underway for many years to develop implantable pressure transducers and sensors for temporary or chronic use in a body organ or vessel. Many different designs and operating systems have been
15 proposed and placed into temporary or chronic use with patients. Indwelling pressure sensors for temporary use of a few days or weeks are available, and many designs of chronically or permanently implantable pressure sensors have been placed in clinical use.

Piezoelectric crystal or piezoresistive pressure transducers mounted at or near
20 the distal tips of pacing leads, for pacing applications, or catheters for monitoring applications, are described in U.S. Patent Nos. 4,407,296, 4,432,372, 4,485,813, 4,858,615, 4,967,755, and 5,324,326, and PCT Publication No. WO 94/13200, for example. The desirable characteristics and applications for patient use of such lead or catheter bearing, indwelling pressure sensors are described in these and other patents
25 and the literature in the field. Generally, the piezoelectric or piezoresistive transducers have to be sealed hermetically from blood. Certain of these patents, e.g. the '296 patent, disclose sealing the piezoresistive bridge elements within an oil filled chamber.

U.S. Patent No. 4,023,562 describes a piezoresistive bridge of four,
30 orthogonally disposed, semiconductor strain gauges formed interiorly on a single crystal silicon diaphragm area of a silicon base. A protective silicon cover is bonded to the base around the periphery of the diaphragm area to form a sealed, evacuated chamber. Deflection of the diaphragm due to ambient pressure changes is detected by the changes in resistance of the strain gauges.

Because the change in resistance is so small, a high current is required to detect the voltage change due to the resistance change. The high current requirements render the piezoresistive bridge unsuitable for long term use with an implanted power source. High gain amplifiers that are subject to drift over time are also required to
5 amplify the resistance-related voltage change.

Other semiconductor sensors employ CMOS IC technology in the fabrication of pressure responsive silicon diaphragm bearing capacitive plates that are spaced from stationary plates. The change in capacitance due to pressure waves acting on the diaphragm is measured, typically through a bridge circuit, as disclosed, for example,
10 in the article "A Design of Capacitive Pressure Transducer" by Ko et al., in IEEE Proc. Symp. Biosensors, 1984, p.32. Again, fabrication for long term implantation and stability is complicated.

In addition, differential capacitive plate, fluid filled pressure transducers employing thin metal or ceramic diaphragms have also been proposed for large scale
15 industrial process control applications as disclosed, for example, in the article "A ceramic differential-pressure transducer" by Graeger et al., Philips Tech. Rev., 43:4:86-93, Feb. 1987. The large scale of such pressure transducers does not lend itself to miniaturization for chronic implantation.

Despite the considerable effort that has been expended in designing such
20 pressure sensors, a need exists for a body implantable, durable, long-lived and low power pressure sensor for accurately sensing absolute pressure waves and related parameters in the body over many years.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a practical and
25 durable indwelling absolute pressure sensor particularly for measuring blood pressure.

In accordance with the invention an implantable capacitive pressure sensor lead for providing signals representative of the magnitude of body fluid pressure at a selected site and ambient operating conditions, including body temperature, at the site comprises: an elongated implantable lead body having proximal and distal end
30 sections and having first and second electrical conductors extending from the proximal end section to the distal end section, the proximal end adapted to be coupled to a biasing signal source, and the distal end section adapted to be implanted in a body

position for measuring a varying body fluid pressure; and a pressure sensor module formed in the distal end section of the lead body and coupled to the first and second electrical conductors, the pressure sensor module further comprising: a module housing attached to the lead body adapted to be positioned in a body cavity and enclosing a hermetically sealed chamber; pressure deformable pickoff capacitor means for varying in capacitance in response to variations in fluid pressure having a first plate formed of a pressure deformable diaphragm of the module housing and a second plate spaced apart therefrom; reference capacitor means having a first plate formed of a non-deformable portion of the module housing and a second plate spaced apart therefrom; a substrate supported within the module housing; pressure and temperature signal modulating circuit means supported on the substrate within the hermetically sealed chamber and electrically coupled to the first and second electrical conductors, the circuit means comprising means for receiving an externally applied biasing signal and generating charging and discharging currents therefrom which vary with ambient temperature, means for alternately charging and discharging the pickoff and reference capacitor means, and means for generating pickoff and reference timing pulses on one of the electrical conductors, the timing pulses separating the alternate charging time intervals of the pickoff and reference capacitor means.

The pressure sensor lead is preferably constructed such that the first plate of the pickoff capacitor means is formed of a pressure deformable, planar diaphragm having a first predetermined surface area formed by the module housing of a conductive material with an exterior planar surface and a parallel interior surface within the hermetically sealed chamber, the planar diaphragm adapted to be deformed in the first predetermined surface area by variations in fluid pressure outside the module housing; and the first plate of the reference capacitor means is formed by a second predetermined planar surface area of the interior surface spaced apart from and co-planar with the first predetermined surface area and substantially non-deformable by variations in fluid pressure outside the module housing. Plated standoffs are employed to separate the first and second plates of the reference and pickoff capacitor means.

The entire lead and module housing are electrically insulated from the body. The insulation over the exterior surface of the diaphragm is effected by a thin,

strongly adhering material that prevents separation and the formation of voids which could fill with liquid and change the response characteristics of the diaphragm to pressure changes.

The construction of the reference capacitor employing an extension of the common plate with the pickoff capacitor and the other plates on the same substrate, with the plates separated by the same separator standoff platings simplifies fabrication. The use of the temperature dependent charging current provides for the determination of the temperature signal which can then be used to derive an absolute pressure signal with the common mode temperature variations accounted for.

BRIEF DESCRIPTION OF THE DRAWING

These and other objects, advantages and features of the present invention will be more readily understood from the following detailed description of the preferred embodiments thereof, when considered in conjunction with the drawings, in which like reference numerals indicate identical structures throughout the several views, and wherein:

Figure 1 is block level diagram of an implantable, programmable blood pressure monitor and lead system of the present invention;

Figure 2 is a cross-section assembly view of the distal end of a pressure sensing lead employed in the system of Figure 1;

Figure 3 is a cross-section assembly view of the proximal end of a pressure sensing lead employed in the system of Figure 1;

Figure 4 is a top subassembly drawing of the pressure sensing module incorporated into the distal end of the pressure sensing lead of Figure 2;

Figure 5 is a side cross-section view of the internal components of the pressure sensing module taken along line A-A of Figure 4;

Figure 6 is a partial cutaway perspective view of the attachment of the pressure and temperature signal modulating circuit to the feedthrough and housing of the pressure sensing module;

Figure 7 is an exploded perspective view of the components of the pressure sensing module;

Figure 8 is a side cross section view of a housing member and diaphragm taken along line B-B of Figure 7;

Figure 9 is a bottom view of the IC hybrid circuit substrate of Figure 7;

Figure 10 is a schematic diagram of the pressure sensing lead impedance network and the pressure and temperature signal modulating circuit;

Figure 11 is a schematic diagram of the pressure and temperature signal
5 modulating circuit;

Figure 12 is a timing diagram of the pulse signals emitted by the circuits of
Figures 11 and 13; and

Figure 13 is a schematic diagram of the demodulator of the pressure monitor of
Figure 1.

10 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The capacitive pressure sensing lead 12 of the present invention is designed to
chronically transduce blood pressure from the right ventricle of the heart over the
range of absolute pressures from 400-900 mm Hg, and within the frequency range of
0-100 Hz. The lead 12 is primarily employed with an implantable, battery powered
15 monitor 100 which employs a microprocessor based demodulation, data storage and
telemetry system for sampling and storing blood pressure data at programmed
intervals and telemetering out the accumulated data to an external
programmer/transceiver on receipt of a programmed-in command, in the manner of
current, conventional multi-programmable pacemaker technology. The lead 12 is
20 intended to be implanted transvenously into the right heart chambers in the same
manner as a conventional pacing lead, except that the distal end, including the
pressure sensor module, may be advanced out of the right ventricle into the pulmonary
artery to monitor blood pressure in that location. The monitor is intended to be
implanted subcutaneously in the same manner that pacemakers are implanted.

25 Monitor and Lead System Overview

Figure 1 is a simplified block diagram of the patient's heart 10 in relation to
the pressure sensing lead 12 and monitor 100. The lead 12 has first and second lead
conductors 14 and 16 extending from a proximal connector end 18 to the pressure
sensor module 20 disposed near the distal tine assembly 26. The pressure sensor
30 module 20 includes a variable pickoff capacitor and a fixed reference capacitor and
signal modulating circuit described below in reference to Figures 4 - 12 which
develops both blood pressure and temperature time-modulated intervals. The proximal

connector assembly is formed as a conventional bipolar, in-line pacing lead connector and is coupled to the monitor connector (not shown) which is formed as a conventional bipolar in-line pacemaker pulse generator connector block assembly. The tine assembly 26 comprises soft pliant tines adapted to catch in heart tissue to stabilize the lead in a manner well known in the pacing art. The detailed construction of the lead 12 is described below in conjunction with Figures 2 and 3.

The monitor 100 is divided generally into an input/output circuit 112 coupled to a battery 108, an optional activity sensor 106, a telemetry antenna 134, the lead conductors 14, 16, a crystal 110, and a microcomputer circuit 114. The input/output circuit 112 includes the digital controller/timer circuit 132 and the associated components including the crystal oscillator 138, power-on-reset (POR) circuit 148, Vref/BIAS circuit 140, ADC/MUX circuit 142, RF transmitter/receiver circuit 136, optional activity circuit 152 and pressure signal demodulator 150.

Crystal oscillator circuit 138 and crystal 110 provide the basic timing clock for the digital controller/timer circuit 132. Vref/BIAS circuit 140 generates stable voltage reference Vref and current levels from battery 108 for the circuits within the digital controller/timer circuit 132, and the other identified circuits including microcomputer circuit 114 and demodulator 150. Power-on-reset circuit 148 responds to initial connection of the circuitry to the battery 108 for defining an initial operating condition and also resets the operating condition in response to detection of a low battery voltage condition. Analog-to-digital converter (ADC) and multiplexor circuit 142 digitizes analog signals Vprs and Vtemp received by digital controller/timer circuit 132 from demodulator 150 for storage by microcomputer circuit 114.

Data signals transmitted out through RF transmitter/receiver circuit 136 during telemetry are multiplexed by ADC/MUX circuit 142. Voltage reference and bias circuit 140, ADC/MUX circuit 142, POR circuit 148, crystal oscillator circuit 138 and optional activity circuit 152 may correspond to any of those presently used in current marketed, implantable cardiac pacemakers.

The digital controller/timer circuit 132 includes a set of timers and associated logic circuits connected with the microcomputer circuit 114 through the data communications bus 130. Microcomputer circuit 114 contains an on-board chip including microprocessor 120, associated system clock 122, and on-board RAM and

ROM chips 124 and 126, respectively. In addition, microcomputer circuit 114 includes an off-board circuit 118 including separate RAM/ROM chip 128 to provide additional memory capacity. Microprocessor 120 is interrupt driven, operating in a reduced power consumption mode normally, and awakened in response to defined interrupt events, which may include the periodic timing out of data sampling intervals for storage of monitored data, the transfer of triggering and data signals on the bus 130 and the receipt of programming signals. A real time clock and calendar function may also be included to correlate stored data to time and date.

In a further variation, provision may be made for the patient to initiate storage of the monitored data through an external programmer or a reed switch closure when an unusual event or symptom is experienced. The monitored data may be related to an event marker on later telemetry out and examination by the physician.

Microcomputer circuit 114 controls the operating functions of digital controller/timer 132, specifying which timing intervals are employed, and controlling the duration of the various timing intervals, via the bus 130. The specific current operating modes and interval values are programmable. The programmed-in parameter values and operating modes are received through the antenna 134, demodulated in the RF transmitter/receiver circuit 136 and stored in RAM 124.

Data transmission to and from the external programmer (not shown) is accomplished by means of the telemetry antenna 134 and the associated RF transmitter and receiver 136, which serves both to demodulate received downlink telemetry and to transmit uplink telemetry. For example, circuitry for demodulating and decoding downlink telemetry may correspond to that disclosed in U.S. Patent No. 4,556,063 issued to Thompson et al. and U.S. Patent No. 4,257,423 issued to McDonald et al., while uplink telemetry functions may be provided according to U.S. Patent No. 5,127,404 issued to Wyborny et al. Uplink telemetry capabilities will typically include the ability to transmit stored digital information as well as real time blood pressure signals.

A number of power, timing and control signals described in greater detail below are applied by the digital controller/timer circuit 132 to the demodulator 150 to initiate and power the operation of the pressure sensor module 20 and selectively read out the pressure and temperature signals V_{prs} and V_{temp} . An active lead conductor

16 is attached through the connector block terminals to input and output terminals of demodulator 150 which supplies a voltage VREG at the output terminal. A passive lead conductor 14 is coupled through to the VDD supply terminal of the demodulator 150. The voltage signals Vprs and Vtemp developed from intervals between current
5 pulses received at the input terminal are provided by demodulator 150 to the digital controller/timer circuit 132. The voltage signals Vprs and Vtemp are converted to binary data in an ADC/MUX circuit 142 and stored in RAM/ROM unit 128 in a manner well known in the art.

As depicted in Figure 1, the monitor 100 periodically stores digitized data
10 related to blood pressure and temperature at a nominal sampling frequency which may be related to patient activity level, both optionally correlated to time and date and patient initiated event markers. The monitor 100 may also optionally include a further lead connector for connection with further lead for implantation in the right heart having an exposed unipolar distal electrode from which an electrogram (EGM) may be
15 derived. The further lead may also have an oxygen sensor module in the distal segment of the lead. Such a lead is shown in commonly assigned U.S. Patent No. 4,750,495 to Moore and Brumwell, incorporated herein by reference. That modification of the monitor 100 would also include an EGM sense amplifier (using the monitor case as an indifferent electrode) and an oxygen sensor demodulator and is also
20 described in the above-incorporated `495 patent.

In that optional configuration, the EGM signal may be employed to identify the onset of a cardiac depolarization in each heart cycle and initiate either the monitoring and storage operations or simply initiate the storage of the data derived by continuous monitoring which would otherwise not be stored. In accordance with the preferred
25 embodiment of the invention, the monitored parameters including patient activity, blood pressure and temperature, blood oxygen or other gas saturation level and EGM are all continuously monitored.

The blood pressure signals are preferably digitized and stored at a sample period of every 4.0 ms or 256 Hz sampling frequency. As shown below, this
30 frequency is about one-tenth of the operating frequency of the sensor module 20. The blood temperature signals are preferably digitized and stored once during every sensed EGM heart depolarization cycle. The digitized data values are stored on a FIFO basis

between periodic telemetry out of the stored data for permanent external storage. Then, the data may be analyzed externally to identify the portions of the cardiac cycle of interest and to perform other diagnostic analyses of the accumulated data. Preferably, the external programmer can also program the monitor 100 to telemeter
5 out the digitized data values in real time at the same or different sampling frequencies.

The sampled and stored blood pressure data are absolute pressure values and do not account for changes in barometric pressure affecting the ambient pressure load on the pressure sensor module 20. Physicians typically measure blood pressure in relation to atmospheric pressure. Thus, it may be necessary to separately record
10 atmospheric pressure data with separate measuring and recording equipment. At present, a separate, portable pressure recording unit (not shown) worn externally by the patient to record atmospheric pressure is contemplated to be used with the system of the present invention. The atmospheric pressure and a time and date tag are preferably recorded in the external unit at periodic, e.g. one minute, intervals. The
15 atmospheric pressure data is intended to be read out from the external unit when the absolute pressure and optional other data stored in RAM/ROM unit 128 is telemetered out and the data correlated by time and date and employed by the physician to derive diagnoses of the patient's condition.

Pressure Sensor/Lead Construction

20 The pressure sensor capsule or module 20 is constructed with a titanium outer housing having an integral, pressure deformable, planar sensing membrane or diaphragm formed in it as one plate of a variable or pickoff capacitor C_p . The other plate of the pickoff capacitor C_p is fixed to one side of a hybrid circuit substrate hermetically sealed within the outer housing. The capacitance of pickoff capacitor C_p
25 varies as the diaphragm is deformed by pressure waves associated with heart beats in the patient's heart 10 or elsewhere in the vascular system. A reference capacitor C_R is also formed with fixed spacing between planar capacitor plates formed on the same side of the hybrid circuit substrate and on the outer housing to provide a reference capacitance value. The pressure (and temperature) sensor circuitry within the module
30 20 employs the voltages VDD and VREG supplied by the demodulator 150 to alternately charge and discharge the capacitor pair with charge and discharge currents that vary with temperature and to provide instantaneous absolute pressure and

temperature modulated charge time intervals to the demodulator 150 in a manner described below.

Figures 2 and 3 are cross-section views of the distal and proximal end sections of the lead 12 of Figure 1. The pressure sensor module 20 is located just proximal to the distal tip tine assembly 26 and is mechanically and electrically connected to the coaxial, outer and inner, coiled wire lead conductors 14 and 16. The passive and active, coiled wire lead conductors 14 and 16 are separated by an inner insulating sleeve 22 and encased by an outer insulating sleeve 46 extending between in-line connector assembly 30 and the pressure sensor module 20. A stylet receiving lumen is formed within the inner coiled wire lead conductor 16 and extends to the connection with the sensor module 20.

The in-line connector assembly 30 includes an inner connector pin 36 having a stylet receiving, pin lumen 38 and is attached to the proximal end of the inner coiled wire conductor 16 to align the pin lumen 38 with the stylet receiving lumen of the inner coiled wire conductor 16. An insulating sleeve 40 extends distally over the inner connector pin 36 and separates it from a connector ring 42. Connector ring 42 is electrically and mechanically attached to the proximal end of the outer coiled wire conductor 14. An exterior insulating connector sleeve 24 extends distally from the connector ring 42 and over the proximal end of the outer sleeve 46.

The distal ends of the outer and inner coiled wire conductors 14 and 16 are attached to the proximal end of the pressure sensor module 20 to provide the VDD and the input/output connections to the on-board pressure sensor hybrid circuit described below. A further coiled wire segment 32 extends between the tine assembly 26 and the distal end of the pressure sensor module 20 and is covered by a further insulating sleeve 34. The tine assembly 26 surrounds and electrically insulates inner metal core 28 that is mechanically attached to the distal end of the coiled wire segment 32.

The materials used for these components of the pressure sensing lead 12 and the construction and attachments depicted in Figures 2 and 3 are conventional in the art of bipolar, coaxial pacing lead technology having an in-line connector. Such lead technology is incorporated in the fabrication of the Medtronic® bipolar pacing lead Model 4004M. The specific materials, design and construction details are not

important to the understanding and practice of the present invention. In this particular illustrated embodiment, the pressure sensing lead 12 is not also employed as a pacing lead, but the pressure sensing module 20 could be incorporated into a pacing lead, particularly for use in control of rate responsive pacemakers and pacemaker-
5 cardioverter-defibrillators.

Turning to the construction of the pressure sensing capsule or module 20, reference is first made to the assembly drawings, including the enlarged top and side cross-section views of Figures 4 and 5, the partial section view of Figure 6 and the exploded view of Figure 7. The pressure sensing module 20 is formed with a first and
10 second titanium outer housing half members 50 and 52 which when joined together as assembled titanium housing 55 surround a ceramic hybrid circuit substrate 60 supporting the sensing and reference capacitors and pressure signal modulating circuit.

The pressure signal modulating circuit (described in detail below with reference to Figures 10 and 11) includes a resistor 62 and IC chip 64 mounted to one surface of the
15 substrate 60 and attached to electrical terminal pads and board feedthroughs to the other surface thereof. The substrate 60 is supported in a manner described below in a fixed relation with respect to housing member 52 by the proximal and distal silicone rubber cushions 70 and 72 and the parallel side walls 47 and 49 (shown in Figures 7 and 8). The proximal silicone rubber cushion 70 also bears against the titanium
20 adaptor ring 74 that receives the feedthrough 76. The feedthrough 76 includes a ceramic insulator 77 between the feedthrough ferrule 79 and feedthrough wire 80 to electrically isolate feedthrough wire 80 that is electrically connected to a pad of the substrate 60. The distal silicone rubber cushion 72 bears against the nose element 78 which is electrically connected to a further pad of the substrate 60.

Internal electrical connections between the sensor IC chip 64 and the substrate
25 are made via aluminum wire-bonds as shown in Figure 6. Connections between the hybrid traces and both the feedthrough pin 80 and the nose element extension pin 75 are also made via gold wire-bonds. Conventional wire-bonding is used with each trace, while the connections to the pins 75 and 80 are made using conductive silver
30 epoxy. The specific electrical connections are described below in conjunction with the electrical schematic diagram of the sensor module electronic circuit in Figure 11.

After the mechanical and electrical components of the pressure sensing module 20 are assembled together, the titanium housing half members 50 and 52 and the nose element and adaptor ring 74 are laser welded together as hermetically sealed, assembled titanium housing 55. Then, the module 20 is attached to the components of the lead 12 to provide the electrical and mechanical connections with the outer and inner, passive and active, coiled wire lead conductors 14 and 16 as described below.

As shown in Figure 2, the module 20 is electrically and mechanically attached to the outer and inner coiled wire conductors 14 and 16 at the proximal end thereof through an intermediate transition assembly similar to a feedthrough and including an insulating body 56 separating an inner, conductive transition pin 58 from distal and proximal outer conductive transition sleeves 57 and 59. Sleeves 57 and 59 are laser welded together for electrical and mechanical connection.

The distal transition sleeve 57 is welded to the ferrule 79 and the distal end of the transition pin 58 is staked to the feedthrough pin 80. The distal end of the inner transition pin 58 is hollow and extends out of the insulating body 56 to receive the proximal end of the feedthrough pin 80. Staking is accomplished through access ports in the molded insulating body 56, and then the access ports are filled with silicone adhesive. In this fashion, the inner transition pin 58 is electrically coupled to the feedthrough pin 80, and the outer transition sleeves 57 and 59 are electrically connected to the assembled titanium housing 55.

The proximal end of the inner transition pin 58 is slipped into the distal lumen of the inner coiled wire conductor 16. The distal end of the inner coiled wire conductor 16 is crimped to the proximal end of the inner transition pin 58 by force applied to a crimp sleeve 66 slipped over the distal segment of the coiled wire conductor 16. The distal end of inner insulating sleeve 22 is extended over the crimp sleeve 66 and adhered to the insulating body 56 to insulate the entire inner conductive pathway. The outer coiled wire conductor 14 is attached electrically and mechanically by crimping it between the outer transition sleeve 59 and an inner crimp core sleeve 68 slipped between the distal lumen of the outer coiled wire conductor 14 and the inner insulating sleeve 22. Silicone adhesive may also be used during this assembly. When the electrical and mechanical connections are made, the active coiled wire conductor 16 is electrically connected to a pad or trace of the substrate 60, and the

passive coiled wire conductor 14 is electrically attached through the housing half members 50 and 52 to a further substrate pad or trace as described below.

The distal end of the pressure sensing module 20 is attached to the distal lead assembly including further outer sleeve 34 and coiled wire conductor 32 described above. At the distal end of the pressure sensing module 20, a crimp pin 81 is inserted into the lumen of the further coiled wire conductor. The crimp pin 81 and the further coiled wire conductor 32 are inserted into the tubular nose element 78 which is then crimped to the coiled wire conductor 32 and crimp pin 81. The further outer sleeve 34 extends over the crimp region and the length of the further coiled wire conductor 32. The distal end of the further coiled wire conductor 32 is attached by a similar crimp to the inner tip core member 28 using a further crimp pin 27.

Returning to Figures 4 and 5, and in reference to Figure 8, thin titanium diaphragm 54 is machined into the titanium outer housing half member 50. The flat inner surface of diaphragm 54 and a peripheral continuation of that surface form plates of a pair of planar capacitors, the other plates of which are deposited onto the adjacent surface 61 of the ceramic hybrid substrate 60 as shown in Figure 9. An external pressure change results in displacement of the diaphragm 54 and subsequent change in capacitance between the diaphragm 54 and one of the deposited substrate plates. This change in capacitance of the pickoff capacitor C_p with change in pressure is approximately linear over the pressure range of interest, and is used as a measure of the pressure outside the sensor module 20. The external pressure change has little effect on the second, reference capacitor C_R .

To electrically isolate diaphragm 54 from the patient's body, materials must be used that do not significantly absorb body fluids and swell, which in turn causes diaphragm 54 deflection and changes the capacitance of the pickoff capacitor C_p . The material must be uniformly thin and repeatable during manufacture so as to avoid affecting sensitivity of the pickoff capacitor C_p . Also, the material must adhere very well to the diaphragm 54 so that bubbles, gaps or other separations do not occur over time. Such separations could cause hysteresis or lag of the sensed capacitance change.

Returning to Figure 2, the outer sleeve 46 and further sleeve 34 are formed of conventional urethane tubes employed in fabricating pacing leads. For adherence to outer sleeve 46 and further sleeve 34, a thin urethane sensor jacket or covering 82 is

employed that extends over the full length of the sensor module 20 and is adhered at its ends to the outer insulating sleeve 46 and the further outer insulating sleeve 34, e.g. as by urethane based adhesives. The urethane covering 82 is employed to cover the majority of the sensor module 20 but the material does not always adhere well to the metal surfaces thereof, even when a primer is employed. The loss of adherence over the diaphragm 54 can lead to accumulation of fluids and affect the response time to changes in blood pressure. Therefore, it is necessary to substitute a better adhering, body compatible, insulating coating over the diaphragm 54.

In order to do so, a cut-out portion of the sensor covering 82 is made following the periphery 53 in order to expose the diaphragm or diaphragm 54. A thin, uniform thickness coating 45 of silicone adhesive is applied over the exposed diaphragm 54 that adheres thereto without any fluid swelling or separation occurring over time. The silicone adhesive does not adhere well to the edges of the cut-out section of the urethane covering 82, but can be injected between the edges and the half member 50 to fill up any remaining edge gap.

The resulting composite covering 82 and insulating layer electrically insulates the titanium outer housing half members 50 and 52 that are electrically connected to VDD. The combined housing is formed by welding the half members 50 and 52 together and to the adaptor ring 74 and nose element 78. When assembled, the sensor capsule or module 20 is preferably about 0.140 inches in diameter, including the polyurethane insulation covering 82, and is approximately 0.49 inches long.

The cylindrical housing half members 50 and 52 are machined in the two pieces using wire electric discharge machining (EDM) methods. In the first housing half member 50, the thin diaphragm 54 is approximately 0.0013 inches thick at T in Figure 8 and is produced through precision EDM of the interior and exterior surfaces of the titanium stock. The inner surface 51 of the half member 50 extends as a continuous planar surface beyond the perimeter 53 of the diaphragm 54 to provide one plate of the reference capacitor C_R in that region.

Turning to Figure 9, the ceramic sensor hybrid circuit substrate 60 consists of a 90% alumina board, on the back side 61 of which are deposited an inner, rectangular capacitor plate 84 coupled to a plated substrate feedthrough 98, an outer, ring shaped capacitor plate 86 coupled to a plated substrate feedthrough 96, and three

plated standoffs 88, 90, 92. The inner capacitor plate 84 is dimensioned to generally conform to the shape of the diaphragm 54 and fall within the perimeter 53. The perimeter or ring-shaped capacitor plate 86 is dimensioned to fall outside or just inside or to straddle the perimeter 53. The inner surface 51 of half member 50 provides a reference surface for locating the capacitor plates 84 and 86 relative to the diaphragm 54.

When assembled, the plates 84 and 86 are spaced from the inner surface 51 of the housing half member 50 by the difference in thicknesses of the standoffs 88 - 92 and the plates 84 and 86 to form the pickoff capacitor C_P and reference capacitor C_R . The pressure sensing pickoff capacitor C_P employing central capacitor plate 84 varies in capacitance with pressure induced displacement of the diaphragm 54 and the silicone adhesive layer applied thereto. The reference capacitor C_R , employing the perimeter reference capacitor plate 86 located in the region where diaphragm 54 deflection is negligible within the operating pressure range, varies in capacitance with common mode changes in sensor voltages, thermal expansion effects, and changes in the hermetically sealed capacitor dielectric constant.

The two capacitor plates 84 and 86 are electrically connected to the front side of the substrate 60, on which the sensor electronic circuit included in the IC chip 64 and the resistor 62 are mounted. The common capacitor plate surface 51 is coupled to VDD. The sensor electronic circuit alternately charges and discharges the pickoff and reference capacitors C_P and C_R through a constant current source which varies with temperature change inside the sensor module 20. The temperature-related changes in the charging current affects the charge times for both the pickoff and reference capacitors C_P and C_R equally. However, temperature induced changes in internal pressure within the sensor module 20 (and external pressure changes) only affect the pickoff capacitor C_P plate spacing, which causes an increase or decrease in the capacitance and subsequent increase or decrease in the time to charge the pickoff capacitor C_P to a set voltage level.

Blood pressure changes cause an increase or decrease of the pickoff capacitor C_P plate spacing, which causes a decrease or increase, respectively, in the capacitance and subsequent decrease or increase, respectively, in the time to charge the pickoff capacitor C_P to a set voltage level, assuming an unchanged blood temperature and

constant charging current. Since no significant gap change between common plate surface 51 and the perimeter capacitor plate 86 due to pressure change occurs at the reference capacitor C_R , there is little pressure induced reference capacitance change. The ratio of the charging time of the pickoff capacitor C_P to the sum charging time of the reference and pickoff capacitors C_R and C_P provides a stable indication of pressure induced changes and cancels out common mode capacitance changes, resulting in an absolute pressure signal. The common mode capacitance change, principally temperature related, can be derived from the capacitance of the reference capacitor C_R . The signals V_{prs} and V_{temp} can also be time correlated to EGM, activity signals and blood gas signals and all stored in memory for later telemetry out.

The substrate surface 61 platings shown in Figure 9 are specially designed to provide precise control of the pickoff and reference capacitor gaps without the need for an excessive number of close-tolerance components. By specifying a single tight tolerance between the top surfaces of the standoff platings and the top surfaces of the capacitor platings, the spacing between the reference and pickoff capacitor plates and the planar surface 51 of the sensor diaphragm 54 can be very accurately controlled. Because the inner surface 51 of the diaphragm 54 extends beyond the perimeter 53 of the diaphragm 54 to the region where the standoffs 88 - 92 make contact, the difference between the height of the standoff pads and the height of the capacitor plates 84 and 86 will define the gap between the capacitor plates 84, 86 and the inner surface 51.

The hybrid standoffs 88 - 92 are pressed into contact against the inner surface 51 by the compressible molded silicone rubber cushions 70, 72 when the components are assembled. The assembly creates an interference fit exerting pressure between the surface 51 and the standoffs 88 - 92. Lateral constraint of the substrate 60 is provided by the fit of the hybrid circuit substrate 60 in the housing half member 50 between the lateral side walls 47 and 49 in one axis, and by the silicone rubber cushions 70, 72 along the other axis. In a variation, the rubber cushions 70, 72 may be eliminated in favor of simply adhering the side edges of the substrate 60 to the side walls 47 and 49 and/or the end edges to the inner surface 51 of the half member 50. Or the adhesive could be used with the rubber cushions 70, 72. Furthermore, in each assembly variation, the standoffs 88 - 92 could be bonded to the inner surface 51. The result is

an accurate and permanent location of the substrate 60 within the cavity of the sensor module 20 with no residual stress in the critical parts which might cause drift of the sensor signal over time.

This approach to spacing the pickoff and reference capacitor C_p and C_r plates has two major advantages. First, only one set of features, that is the plating heights or thicknesses, need to be in close tolerance, and those features are produced through a process which is extremely accurate. For, example, the standoffs 88, 90, 92 can be precisely plated to a thickness of 0.0011, and the capacitor plates 84, 86 can be plated to 0.005 inches. A gap of 0.0006 inches with a tolerance of 0.0001 inches can thereby be attained between the capacitor plates 84, 86 and the diaphragm inner surface 51. The second advantage is the near absence of signal modulation by thermal expansion effects. Thermal change in dimension of the structure which establishes the gap between the plates 84, 86 and the sensor diaphragm inner surface 51 is per the relation $\Delta l = \alpha \Delta T l$, where Δl is the change in gap, α is the thermal expansion coefficient of the material creating the gap, ΔT is the variation in temperature, and l the length of the structure.

In the example provided, the gaps are only 0.0006" thick, so change in gap over an expected variation in temperature in vivo of 1° C, assuming coefficient of thermal expansion for the standoff material of around $13 \times 10^{-6}/^{\circ}\text{C}$, would result in a gap change of 7.8 nano-inches. This thermal change is about sixty times less than the gap change for 1 mm Hg pressure change, and much less than be detected using state of the art low-current methods.

There is one significant thermal effect. When the pressure sensor module 20 is sealed using a laser weld process, a volume of gas (mostly Argon and Nitrogen) at or near atmospheric temperature and pressure is trapped inside the cavity of the sensor module 20. The difference between the gas pressure inside the cavity and the outside pressure influences the gap of the pickoff capacitor C_p . At the instant the sensor is sealed, there is zero pressure differential and consequently no deflection of the pressure diaphragm 54 from its neutral position. But the gas inside the sensor must comply with the classical gas law $PV = nRT$. Assuming then that the volume inside the sensor is constant, and that the mass quantity and gas constant (n and R , respectively) are constant (since no gas enters or leaves the sensor cavity after

sealing), the effect of temperature change can be described by the gas law formula as $P_2 = P_1 (T_2/T_1)$.

In the human body, and particularly the venous blood stream in the ventricle, the temperature may vary from the nominal 37 °C (± 2 °C). The variation may be
5 between ± 3 °C with fever and between -1 °C to +2 °C with exercise. Assuming that the sensor were sealed at 300K and 760 mm Hg, the gas law formula implies that for every 1° C change in temperature there is a corresponding change of over 2 mm Hg in internal pressure. This will manifest itself as a decrease in the pressure value reported by the sensor with increasing temperature, since the cavity pressure against which
10 external pressure is compared has increased. This is a significant error and needs to be compensated for. In accordance with a further aspect of the present invention, the charging time of the reference capacitor C_R , which will vary as a function of temperature due to variation of band-gap regulator current of approximately 1% / °C, is monitored. The change in charging time T_{temp} of the reference capacitor C_R is
15 stored in the monitor 100, and used to correct for changing temperature effects.

As previously mentioned, the feature which physically responds to pressure to produce a change in pickoff capacitance is the thin diaphragm 54 in housing half member 50 created via a wire EDM process. The deflection y measured at the center of the diaphragm 54 is governed by the equation:

20
$$y_{max} = k_1 (wr^4 / Et^3)$$

where w is the pressure applied to one side of the diaphragm 54 (or the pressure difference), r is the width of the rectangular diaphragm 54, E is Young's Modulus for the diaphragm material, t is the thickness of the diaphragm, and k_1 is a constant determined by the length-to-width ratio of the diaphragm 54. In the present invention,
25 a ratio of 2:1 was used for the sensor diaphragm 54 dimensions, yielding $k_1 = .0277$. If the ratio were reduced to 1.5:1, and width remained constant, k_1 would be reduced to .024, with a corresponding 13% reduction in diaphragm displacement. This is not a major impact on sensitivity, and shows that the length of the diaphragm 54 could potentially be reduced without a major impact on sensitivity.

30 In a specific construction employing the 2:1 ratio and a diaphragm thickness T of 0.0013 inches, and a gap of 0.005 inches, a baseline capacitance of approximately 3 pF was realized for both the pickoff and reference capacitors, C_P and C_R counting a

capacitance contribution of the sensor IC chip 64. Baseline capacitance is preferably large in comparison to expected parasitic capacitances, especially those which would tend to vary over time or in response to environments, but not so large as to demand overly large charging currents. Also, the capacitances are preferably large enough to keep the oscillation frequency of the pickoff circuit around 4-6 kHz without resorting to extremely low charging currents, which would tend to decrease signal-to-noise ratio. Preliminary prediction for change in capacitance in response to pressure change is 0.5 - 1.5 fF / mm Hg.

The preferred embodiment of the reference and pickoff capacitors described above and depicted in the drawings, particularly Figure 9, positions the reference capacitor plate 86 in a ring shape surrounding the pickoff capacitor plate 84 on substrate surface 61. It will be understood that the reference capacitor plate 86 may have a different shape and be positioned elsewhere on the substrate surface 61. For example, both the reference capacitor plate 86 and the pickoff capacitor plate 84 may be square or rectangular and positioned side by side on the substrate surface 61. Regardless of the configuration or position, the reference capacitor plate would be located outside the perimeter 53 of the diaphragm 54 and spaced away from the inner surface of the diaphragm 54 in the same fashion as described above. Moreover, in any such configuration, the diaphragm 54 and the pickoff capacitor plate 84 may also have a different shape, e.g. a more square shape than shown.

Pressure and Temperature Signal Modulating Circuit

The pressure and temperature signal modulating sensor circuit 200 (including the circuit within the IC chip 64, the associated resistor 62 mounted on the substrate 60 and the pickoff and reference capacitors C_p and C_r) within pressure sensing module 20 is shown in Figures 10 and 11. Sensor circuit 200 translates the pressure and temperature modulated pickoff and reference capacitor C_p and C_r values into charge time-modulated intervals T_{prs} and T_{temp} , respectively, between sensor current pulse signals P_r and P_p , transmitted up the active lead conductor 16.

Figure 10 also depicts the equivalent circuit impedance of the pressure sensing lead 12 within the dotted line block denoted 12. The lead conductors 14 and 16 can exhibit a leakage resistance 202 as low as about 300kW and capacitance 204 of about 110 pf between them. Lead conductor 14 has a series resistances 206 and 208 totaling

about 25W, and lead conductor 16 has a series resistances 210 and 212 totaling about 40W. The leakage resistance and capacitance may deviate over the time of chronic implantation. The demodulator 150 includes lead load impedances and is calibrated at implantation in a manner described below.

5 The passive lead conductor 14 applies VDD from demodulator 150 to the VDD terminal of IC chip 64 and to the pickoff and reference capacitors C_P and C_R . The active lead conductor 16 connects the terminal VREG of IC chip 64 to the terminals CPOUT and CPIN of demodulator 150 through an equivalent resistor network depicted in Figure 13.

10 The pressure and temperature signal modulating sensor circuit 200 is shown in greater detail in Figure 11 and essentially operates as a bi-stable multivibrator operating near the target frequency of 5 kHz in alternately charging plate 86 of reference capacitor C_R and plate 84 of the pickoff capacitor C_P from VDD, which in this case is 0 volts, through reference voltage VR and to a target voltage VT through a
15 current source of $1/3 I$ as shown in the two waveforms of Figure 12 labeled VC_R and VC_P . The reference capacitor C_R and the pickoff capacitor C_P are alternately discharged through a further current source of $2/3 I$ coupled to VDD through the reference voltage VR back to VDD or 0 volts as also shown in these two waveforms of Figure 12. It should be noted that the wave forms of Figure 12 are not to scale and
20 are exaggerated to ease illustration of the signals generated in the sensor circuit 200 and the demodulator circuit 150.

 The pickoff and reference capacitors C_P and C_R are both nominally 2.2 pF, but approach 3.0 pF with stray capacitances. Due to the biasing convention employed, the reference capacitor C_R and the pickoff capacitor C_P are considered to be
25 discharged when their plates 86 and 84, respectively, are both at VDD or 0 volts. The common plate 51 is always at VDD or 0 volts. The reference and pickoff capacitors C_R and C_P are considered to be charged (to some charge level) when the plates 84 and 86 are at a voltage other than 0 volts. In this case, the charges are negative charges between VDD and VREG or between 0 and -2.0 volts. Thus, the
30 convention employed dictates that reference and pickoff capacitors C_R and C_P are "charged" toward -2.0 volts and "discharged" from a negative voltage toward 0 volts.

The principle involved is also applicable to a VSS convention, where the charged voltage levels would be positive rather than negative in polarity.

In practice, when demodulator 150 of Figure 13 is powered up, it supplies the voltage VDD at 0 volts to lead conductor 14 and VREG at -2.0 volts to lead conductor 16 of the lead 12. The regulated voltages VDD and VREG supplied by the demodulator 150 to the sensor 200 of Figure 11 are applied to a voltage dividing diode network including diodes 214, 216, and 218 and current source 232 in a first branch, diode 220, external resistor 62, and current source 234 in a second branch, and diode 222 and current source 236 in a third branch. Voltage VT is three diode forward voltage drops lower than VDD through diodes 214, 216 and 218, or about -1.5 volts, and voltage VR is two diode forward voltage drops lower than VDD through diodes 214 and 216 or about -1.0 volts.

Differential current amplifier 230 is coupled to the second and third branches and its output is applied to current sources 232, 234 and 236 in each branch. The current I is defined by the voltage difference between two diodes 220 and 222 operating at significantly different current densities, divided by the value of the chip resistor 62. Changes in ambient temperature affect the diode resistances and are reflected in the output signal from differential amplifier 230. Current sources 234, 236 are driven to correct any current imbalance, and current source 232 develops the current I reflecting the temperature change within the sensor module 20.

The principle employed in the pressure and temperature signal modulating sensor circuit 200 is a deliberate misuse of the band gap regulator concept, in that rather than using the band gap method to create a current source insensitive to temperature, the current source 232 varies a known amount, about 1% / °C, with variation in temperature. This allows the variation in the reference capacitor C_R charge-modulated time Ttemp to be used as a thermometer, in the interest of correcting for sensor internal pressure change with temperature and subsequent absolute pressure error affecting the gap, and hence the capacitance, of the pickoff capacitor C_P . Since the gap of the reference capacitor C_R cannot change significantly with pressure or temperature, the primary change in Ttemp can only occur due to temperature induced change in current I generated by current source 232.

The reference voltage VR and the target voltage VT are applied to the switched terminals of schematically illustrated semiconductor switches 258 and 260. The common terminals of semiconductor switches 258 and 260 are coupled to a positive input of comparators 240 and 242, respectively. The negative terminals of comparators 240 and 242 are coupled through the series charge resistors 244 and 246, respectively, to the plates 84 and 86 of the pickoff capacitor C_P and the reference capacitor C_R , respectively. The outputs of the comparators 240 and 242 are inverted by inverters 248 and 250, respectively, and applied to inputs of the flip-flop 252. The outputs of the flip-flop 252 are applied to control terminals of the schematically illustrated semiconductor switches 254 and 256. Semiconductor switches 254 and 256 are bistable in behavior and alternately connect current source 272, providing $2/3 I$, and current source 274, providing $1/3 I$, to the reference capacitor C_R and the pickoff capacitor C_P depending on the state of flip-flop 252. When the current source 272 is applied to one of the capacitors, the current source 274 is applied to the other capacitor. The capacitor voltage on plate 84 or 86 is discharged through current source 272 back to VDD or 0 volts while the capacitor voltage on plate 86 or 84, respectively, is charged through current source 274 toward VT as shown in Figure 12.

The outputs of comparators 240 and 242 are also applied to control the states of schematically illustrated semiconductor switches 258, 260, 262, 263 and 264. Semiconductor switches 258 and 260 are monostable in behavior and switch states from the depicted connection with target voltage VT to reference voltage VR each time, and only so long as, a high state output signal is generated by the respective comparators 240 and 242. The timing states of these switches 258 and 260 closed for conducting VR or VT to respective comparators 240 and 242 are also shown in the wave forms labeled 258 and 260 shown in Figure 12.

The outputs of comparators 240 and 242 are normally low when the capacitor charge voltages VC_P and VC_R , respectively, applied to the positive terminals are lower, in an absolute sense, than the voltages VT applied to the negative terminals. The charging of the capacitor C_P or C_R coupled to the charge current source 274 to the voltage VT or -1.5 volts causes the associated comparator 240 or 242 to go high. When the comparator goes high, the flip-flop 252 changes state exchanging the closed states of semiconductor switches 254 and 256, thereby causing the previously charging

(or fully charged) capacitor to commence discharging and causing the previously discharged other capacitor to commence charging.

The high output state of the associated comparator remains for a predetermined capacitor discharge time period from VT to VR providing a one-shot type, high state output. When the capacitor C_P or C_R voltage discharges to VR, the high state output of the respective comparator 242 or 240 is extinguished, and semi-conductor switches 258 or 260 is switched back to apply VT to the respective negative terminal of the comparator 240 or 242. However, the capacitor C_P or C_R continues to discharge until the plate 84 or 86, respectively, is back at full discharge or 0 volts. Since the discharge rate exceeds the charge rate, there is a period of time in each cycle that the capacitor C_P or C_R remains at 0 volts while the other capacitor charges toward VT (as shown in Figure 12). This ensures that each capacitor is fully discharged to 0 volts at the start of its respective charge time interval.

As shown specifically in Figure 11, the switches 258 and 260 are set to apply the voltage VT to comparators 240 and 242, and the switches 262, 263 and 264 are all open. The plate 84 of pickoff capacitor C_P is connected with the $2/3 I$ current source 272 and is being discharged toward VDD, that is 0 volts, while the plate 86 of reference capacitor C_R is connected with the $1/3 I$ current source 274 and is being charged toward VT or -1.5 volts. Because of the arrangement of the switches, 258, 260, 262, 263, and 264, no pulses are being generated. It can be assumed that the plate 84 of pickoff capacitor C_P is being charged from VDD toward VR and that the voltage on the plate 86 of reference capacitor C_R is discharging from VR toward VDD. When the output of comparator 242 does go high, the high state signal will cause switch 260 to switch over from the then closed pole position (e.g. the pole position schematically depicted in Figure 11) to the other open pole position and remain there until the comparator 242 output goes low again when the capacitor voltage falls back to VT. Similarly, when the output of comparator 240 goes high in the following charge cycle, the high state signal causes switch 258 to switch over from the then closed pole position (e.g. the pole position schematically depicted in Figure 11) to the other pole position and remain there until the comparator 240 goes low. In this fashion, the reference voltage VR is alternately applied by switches 258 and 260,

respectively, to the negative terminals of comparators 240 and 242 for the relatively short VR to VT discharge times shown in Figure 12.

To summarize, when the charge voltage on the pickoff capacitor C_P reaches VT, the comparator 240 switches its output state high, in turn changing the state
5 switch 258 and closing switch 263. Delay circuit 270 is enabled to close switch 264 when switch 263 re-opens. Similarly, in the next cycle, when the voltage on reference capacitor C_R reaches VT, the comparator 242 switches its output state high, changing the state of switch 260 and closing switch 262.

Normally open semiconductor switches 262 and 263 are also monostable in
10 behavior and are closed for the duration of the comparator high state, that is, the VT to VR discharge time period. When closed, the timing current pulses P_R and P_P separating (at their leading edges) the reference and pickoff charge-time modulated intervals Ttemp and Tprs also shown in Figure 12 are generated.

The timing current signal pulse P_P is controlled in width by the reference
15 capacitor C_R capacitor discharge time from VT to VR as shown in the Sensor Current line of Figure 12. The initial low amplitude step of two step timing current signal pulse P_R is also controlled in width by the reference capacitor C_R capacitor discharge time from VT to VR as shown in the wave form labeled Sensor Current in Figure 12.

The VT to VR discharge times, which govern the closed time periods of switches 258
20 and 260 and the widths of the low amplitude steps of the timing current pulses P_R and P_P , are nominally 8-12 msec. The high amplitude step of two step timing current signal pulse P_R is controlled in width by delay circuit 270 of Figure 11.

The high state signal output of comparator 242 therefore closes normally open
25 switch 262 for the duration of the high state, i.e. the VT to VR discharge time of reference capacitor C_R . When switch 262 closes, the current source 266 providing 64 I is applied to the VREG terminal, resulting in the generation of the timing current pulse P_P depicted in Figure 12 appearing on conductor 16 as a sensor current.

Similarly, the high state signal output of comparator 240 also closes the normally open
30 switch 263 for the VT to VR discharge time of duration of pickoff capacitor C_P and is applied to the delay circuit 270. Delay circuit 270 effects the closure of switch 264 at the end of the high state and then maintains closure of the switch 264 through a delayed high state time period. When switches 263 and 264 are sequentially closed,

the current source 266 providing 64 I is applied to the VREG terminal, and then the current source 268 providing 208 I is applied to the VREG terminal. In this manner, the stepped current timing pulse P_R depicted in Figure 12 is generated.

5 The nominal pulse height of 8.0 mA for timing current pulse P_P and for the initial step of timing current pulse P_R is effected by the 64 I current source 266 when either switch 262 or 263 is closed. The nominal, pulse height of 24.0 mA (stepped up from the initial 8.0 mA step) of pulse P_R is effected by the 208 I current source when switch 264 is closed after switch 263 reopens. Between pulses, a baseline supply current of 1.5 mA is present at VREG and on lead conductor 16 to which the current pulse heights or sensor current amplitudes are referenced.

10 The 8.0 mA leading step of pressure-related timing current pulse P_P matches the slew rate of the 8.0 mA peak of temperature-related, reference timing current pulse P_R , which reduces errors that would otherwise be associated with detection of different amplitude pulses having differing slew rates. The rise time of both of the pulses appears to be the same to the current sensor 154 in the demodulator 150. The start of each pulse can therefore be accurately detected and employed as the start and end times for the intervening charge time intervals T_{prs} and T_{temp} . The differing peak amplitudes of the two pulses are readily distinguishable to determine the order of the intervals.

20 Thus, Figure 12 illustrates the waveforms at the switches 258, 260, 262, 263 and 264 in relation to the charge and discharge voltage waveforms of the reference and pickoff capacitor C_R and C_P as well as the timing current pulses P_P and P_R generated at the terminal VREG marking the starts of the respective capacitor charging intervals T_{prs} and T_{temp} .

25 At 37° temperature and a barometric pressure of 740 mm Hg, the capacitance values of capacitors C_P and C_R are approximately equal. Therefore, both capacitors C_P and C_R charge at an approximately equal rate. The intervals between timing signal pulses P_P and P_R are approximately equal, reflecting a 50% duty cycle (calculated as the ratio of T_{prs} to $T_{temp} + T_{prs}$), and the nominal operating frequency from P_P to P_P is 5 kHz.

30 After implantation, the temperature should vary somewhat from 37°. The current I, which changes with temperature change, affects the charge times T_{temp} and

T_{prs} equally which changes the operating frequency. In addition, the blood pressure change between systole and diastole alters the capacitance of the pickoff capacitor C_p which only affects the charge time T_{prs} . Thus, charge time T_{temp} only changes with temperature, and the combined result is a change in frequency and duty cycle
5 dependent on both temperature and pressure changes.

The schematically illustrated current sources and semiconductor switches may be readily realized with conventional integrated circuit designs.

Demodulator Circuit

The demodulator 150 shown in Figure 13 supplies the voltages VDD and
10 VREG, at a baseline current drain from sensor IC chip 64 of about 1.5 mA, to the lead conductors 14 and 16 and receives the timing signal current pulses P_p and P_r modulating the baseline current on conductor 16. The demodulator 150 converts the charge time intervals T_{prs} and T_{temp} separating the leading edges of the train of current pulses of Figure 12 into voltage signals V_{prs} and V_{temp} , respectively. The
15 voltage signals V_{prs} and V_{temp} are supplied to the digital controller/timer circuit 132 and are converted by ADC/MUX circuit 142 into digital values representing absolute pressure and temperature data, which are stored in the microcomputer circuit 114 in a timed relationship with other monitored physiologic data.

As described above, the analog temperature signal V_{temp} is derived from the
20 interval T_{temp} between the leading edges of P_r and P_p in an integration process, and the analog pressure signal V_{prs} is derived from the interval T_{prs} between the leading edges of P_p and P_r in a duty cycle signal filtering and averaging process. In these processes, the demodulator 150 creates the intermediate voltage square waves NCAPS_OUT, NRESET_OUT, and DCAPS shown in Figure 12 from the current
25 pulse timing intervals. The voltage signal V_{temp} can be determined from a relatively simple integration of a time interval related to the time interval T_{temp} . The voltage signal V_{prs} is derived by low pass filtering the square waves of the DCAPS signal representing the time intervals T_{prs} and T_{temp} to obtain the average voltage.

The temperature related capacitance changes are specified to be in a narrow
30 range of $37^{\circ}\text{C} \pm 5^{\circ}\text{C}$ which could effect an ideal gas law pressure variation of 20 mm Hg full scale over the 10°C temperature change. The limited range of the A/D conversion provided by the ADC/MUX circuit 142 and the trimmed slope of the

temperature channel integrator causes a T_{temp} to range between 66 msec to 116 msec in a first range and between 96.5 msec to 146.5 msec in a second range. The resulting voltage range of the analog signal V_{temp} produced at the output of the temperature processing channel is specified to be from 0 to 1.2 volts to be processed by the ADC/MUX circuit 142.

The blood, ambient (atmospheric, altitude, meteorologic) pressure changes affecting the pickoff capacitor are specified in a preferable total range of 400 to 900 mm Hg. The DAC offset adjustment allows the pressure system to be adjusted under user and/or software control to provide this total range in order to be compatible with the more limited range of the 8 bit A/D converter.

In practice the gain of the pressure system will be adjusted dependent on the sensitivity of the particular pressure sensor in order to provide an A/D pressure "range" that encompasses the expected blood pressure range of the patient plus expected local meteorologic pressure changes and expected altitude pressure changes seen by the patient. the blood pressure is normally expected to be -10 mm Hg to 140 mm Hg of gauge pressure (relative to ambient).

The resulting voltage range of the analog signal V_{prs} produced at the output of the absolute pressure signal processing channel is also specified to be from 0 to 1.2 volts to be processed by the ADC/MUX circuit 142.

Turning again to the demodulator circuit 150 of Figure 13, it receives a number of biasing and command signals from the digital controller/timer circuit 132, supplies the voltages V_{DD} and V_{REG} to the pressure and temperature signal modulating circuit 200, processes the sensor current pulses P_R and P_P , and provides the analog signals V_{temp} and V_{prs} to the digital controller/timer circuit 132.

Commencing first with the biasing and operating input signals, the demodulator circuit 150 receives the regulated voltage signal V_{REF1} at +1.2 volts, a current signal I_{in} of 20 nA, and a command signal PSR ON at the power supply 156. The regulated voltage V_{REF1} is the same reference voltage as is employed by the ADC/MUX circuit 142 for digitizing the analog voltage signal between 0 and +1.2 volts into an 8-bit digital word having 0 - 255 values. The output signals V_{prs} and V_{temp} therefore must fall in this range of 0 - 1.2 volts to be processed. It is simpler then to develop accurate regulated voltages and currents of the demodulator 150 from that same

regulated voltage. In addition, it should be noted that the demodulator circuit 150 as well as the other circuits of the monitor 100 including the microcomputer circuit 114 are referenced to VSS or battery ground which is at 0 volts. Therefore, the conventions are reversed from those prevailing in the sensor circuit 200. It will be understood that the same convention could be used in both cases.

From this source, the power supply 156 develops the voltage VREF2 at -2.0 volts below VDD (VDD-2.0 volts), VREG1 at +2.0 volts, and the regulated current signals **Iac**, **Iamp1**, **Iamp2**, **Iamp3**, and **Iic** that are applied to the circuit blocks of Figure 13. The off-chip capacitor and resistor networks 155, 157 and 159, 161 provide bias controls ITEMP for the current **Iic** and ISET for the current **Iac**, respectively. The resistor 159 is selected to provide the **Iac** current to develop specific current thresholds described below for the AC current sensor 154. The resistor 157 is trimmed at the manufacture of each monitor 100 to provide a specific current level **Iic** for the integrator controller 174.

The POR and 32 kHz clock signals are applied on power-up of the monitor 100. The command signal PSR ON, and other command signals TMP ON, 2-BIT GAIN, 4-BIT GAIN, 8-BIT DAC CNTRL, SELF CAL, PLRTY and RANGE are provided to the demodulator circuit 150 by the digital timer/controller circuit 132 from memory locations within the microcomputer circuit 114. Programmed-in commands dictate the operating states and parameters of operation reflected by these command signals. Command signal values and states are stored in microcomputer 114 in memory locations that are accessed from the digital timer/controller circuit 132 and supplied to the demodulator circuit 150 in three words. A GAIN word of 6 bits (2-BIT GAIN & 4-BIT GAIN), a DAC word of 8 bits and a CONTROL word of 6 bits (POR, PSR ON, TMP ON, SELF CAL, RANGE, PLRTY) are stored to set the operating states and selected parameters of operation.

For example, the pressure and temperature sensing functions can be separately programmed ON or OFF or programmed ON together by the PSR ON and TMP ON signals. The 1-bit PSR ON command enables the bias currents **Iamp1**, **Iamp2**, **Iamp3** to operate the pressure signal processing channel. The 1-bit TMP ON command enables the integrator controller 174 to operate the temperature signal

processing channel. The remaining command values and states will be explained in context of the components of the demodulator circuit 150.

Turning to the processing of the sensor current pulses P_P and P_R , the lead conductor 14 is connected to the connector block terminal 15 which is also connected to VDD. The lead conductor 16 is connected to the VREG connector block terminal 17. A load resistor 153 is coupled across connector block terminals 15 and 17 and between VDD and VREG in order to obtain a 2.0 volt drop and to reduce the effects associated with changes in the lead leakage resistance 202. The lead conductor 16 at connector block terminal 17 is connected through resistors 151 and 152 to one input terminal CPIN of the AC current sensor 154 and through resistor 151 alone to the output terminal CPOUT connected to a current sink in the AC current sensor 154.

A further input terminal of AC current sensor 154 is connected to the voltage VREF2 at (VDD-2.0) volts developed by power supply 156. The current sensor 154 operates as a voltage regulator for ensuring that the voltage at CPOUT remains at VREF2 or (VDD-2.0) volts at all times, regardless of the effect of the current pulses P_P and P_R generated during charge of the capacitors C_P and C_R as described above and appearing on conductor 16 at connector block terminal 17. Since the voltage drop across resistor 151 is small, VREG of the circuit 200 in Figure 11 may be viewed as VREF2 of the demodulator circuit 150 of Figure 13. Resistor 151 provides protection against external overdrive due to electromagnetic interference or cardioversion/defibrillation pulses.

The current sensor 154 also includes comparators established by the current I_{ac} that discriminate the amplitudes of current pulses P_P and P_R when they appear and generate the output signals CAPS_OUT and RESET_OUT. The signal amplitudes are discriminated and reduced to current levels established by the comparators and reference current sources in AC current sensor 154. The CAPS_OUT signal is developed in response to both of the low and high amplitude current pulses P_R , and the RESET_OUT signal is developed in response to the high amplitude current pulse P_R only.

The discrimination of the distinguishing parameters of the current pulses P_P (8.0 mA) and P_R (8.0 mA followed by 24.0 mA) is effected by amplitude comparators in AC current sensor 154 that are set by current I_{ac} provided by power supplies 156.

The resistor 159 determines the current ISET which in turn determines the current I_{ac} and the thresholds for the input current pulses in the AC current sensor 154.

Preferably, a low current threshold I_L of +3.6 mA and a high current threshold I_H of +14.4 mA are established for the 8.0 mA and 24.0 mA nominal current pulse amplitudes. The ratio of these two thresholds cannot be changed, but their values are set by resistor 159 to allow for variances in the actual peak step amplitudes of the current pulses P_P and P_R .

A sensor current pulse P_P or P_R having a step that exceeds the I_L (+3.6 mA) low threshold generates an output signal at CAPS_OUT, whereas the high step of current pulse P_R that exceeds the I_H (+14.4 mA) high threshold generates an output signal at RESET_OUT. The CAPS_OUT and RESET_OUT signals are applied to the level shifter 158 which responds by normalizing the signals between VSS or 0 volts and VREG1 of +2.0 volts and providing the NCAPS_OUT and NRESET_OUT signals shown in Figure 12. The normalized NCAPS_OUT and NRESET_OUT signals are applied to the clock and reset inverting inputs, respectively, of flip-flop 160. The inverting inputs effectively invert the depicted NCAPS_OUT and NRESET_OUT signals shown in Figure 12. The flip-flop 160 responds by providing a square wave output signal CAPS (not shown in Figure 12) at its Q-output that is high during the interval T_{prs} and low during the interval T_{temp} .

In the decoding of the T_{temp} and T_{prs} intervals from the current pulse peaks P_P and P_R , the NCAPS_OUT signal is applied to inverting clock input of flip-flop 160 to cause it to switch state. The NRESET_OUT signal is applied to the inverting reset input of flip-flop 160 and does not cause it to change state when its state at the Q output is already low. If, however, the Q output state is high on arrival of NRESET_OUT, the flip-flop 160 state is switched low, resulting in the high state of the DCAPS square wave signal as shown in the first instance in Figure 12. The high amplitude phase of current pulse P_R therefor synchronizes the state of the DCAPS square wave signal on power up and restores any loss of synchronization that may occur from time to time. Once synchronization is established, each successive 8 mA step of the respective current pulse peaks P_P and P_R shown in Figure 12 switches the Q output state of the flip-flop 160, causing the square wave of the CAPS and DCAPS signals reflecting the T_{temp} and T_{prs} intervals.

The CAPS square wave output signal is applied to a digital signal processor 162 and is normally inverted to provide the DCAPS signal shown in Figure 12 at a first output. The digital signal processor 162 also normally inverts the CAPS signal to provide the TREF signal at a second output. In this fashion, the Tprs interval of DCAPS provided to the input of pressure signal processing channel 163 is negative in polarity, and the Ttemp interval of TREF provided to the input of the temperature signal processing channel 164 is positive in polarity. In regard to the polarities of signals DCAP and TREF, the digital signal processor 162 also receives the PLRTY signal from the digital controller/timer circuit 132. The PLRTY signal may be selectively programmed to invert the polarity of the DCAPS square wave in order to increase the operating range of the pressure signal processing channel 163. However, it is expected that the PLRTY signal would seldom be changed, and such a programming option may be eliminated if the range provided in the pressure signal processing channel 163 is sufficient.

As described further below, a self calibration mode can be initiated in response to a SELF CAL signal to apply a 5.46 kHz square wave signal through the digital signal processing circuit 162 to the temperature integrator controller 174 for calibration purposes. The 5.46 kHz square wave signal is simply chosen for convenience, since it is an even sub-multiple of the 32 kHz clock frequency and is close to the nominal 5 kHz operating frequency. The following discussion assumes first that the temperature processing channel 164 is already calibrated in the manner described below and that the normal operating mode is programmed (SELF CAL off) so that only the CAPS signal is processed by the digital signal processor 162.

Addressing the derivation of the signal Vtemp by the temperature signal processing channel 164 first, the temperature is demodulated from the high state of the TREF square wave signal having a duration directly relating to the charge time Ttemp. The integrator controller 174 employs the current Iic to charge an integrator capacitor 187 over the time Ttemp (or a portion of that time as explained below) and then charges sample and hold capacitor 190 to the voltage on integrator capacitor 187. The voltage on integrator capacitor 187 is then discharged and the voltage on sample and hold capacitor 190 is amplified by temperature amplifier stage 195 to become the Vtemp signal in the range of 0 - 1.2 volts.

More particularly, when the integrator capacitor 187 is not being charged or the voltage transferred to the sample and hold capacitor 190, both plates of the integrator capacitor 187 are held at VREG1 and the bidirectional switch 176 is open. Again, the discharge state is characterized as a state where there is no net voltage or charge on the capacitor 187, and the charged state is characterized by a net voltage difference across its plates, even though the "charged" voltage may be nominally lower than the "discharged" voltage.

When the TREF signal goes high (and the low range is programmed), the integrator controller 174 commences charging the plate of integrator capacitor 187 connected to resistor 188 to a voltage lower than VREG1 through a current sink to VSS internal to integrator controller 174. At the end of the high state of the TREF signal, the current sink to VSS is opened and the bidirectional switch 176 is closed for one clock cycle time (30.5 msec) to transfer the resulting voltage level on capacitor 187 to capacitor 190. Bidirectional switch 176 is then opened, and capacitor 187 is discharged by setting both plates to VREG1 through switches internal to integrator controller 174. With each successive recharge of integrator capacitor 187, the capacitor 187 voltage level achieved varies upward and downward from its preceding voltage level with changes in the width of the high state of the TREF signal, and the new voltage level is transferred to capacitor 190. The new voltage level is held on capacitor 190 when the switch 176 is opened.

The switching of bidirectional switch 176, resistor 188 and capacitor 190 also form a low pass filter. The pass band of this filter is sufficient to allow only the temperature related component of the signal to pass through and be reflected on capacitor 190.

The resulting voltage on capacitor 190, amplified by amplifier stage 195, provides the Vtemp signal representing the temperature in the pressure sensor cavity. Amplifier stage 195 includes an amplifier 178 referenced back to approximately +1.2V through the voltage divider comprising resistors 191, 192, 193 dividing the VREG1 of +2.0 volts. Amplifier stage 195 has a gain of two, and so the maximum voltage which the sample and hold capacitor 190 can reach is +0.6V. This corresponds to a +0.6 volt level on integrating capacitor 187 at its junction with resistor 188 which is achieved in 116 msec employing the regulated current Iic.

Two operating ranges provide a higher resolution of the possible values of the reference capacitor C_R charging time T_{temp} reflected by the high state of the TREF signal. Either a high or low range must be programmed by the RANGE bit based on individual sensor circuit 200 characteristics and/or the temperature range of the patient. Since a 5° C change in temperature will result in approximately 5% change in T_{temp} , the 8-bit ADC count provided by ADC/MUX circuit 142 in response to V_{temp} for a particular lead cannot be near the limits of 0 and 255.

For this reason, both the high range and low range for the temperature are provided, and one or the other is selected via a one-bit value of the above-referenced 6-bit CONTROL word. Setting the RANGE bit to 1 places integrator controller 174 in the high range mode which corresponds to a TREF high state pulse width of 96-146 msec. Programming the RANGE bit to 0 places integrator controller 174 in the low range mode which corresponds to a TREF high state pulse width of 66-116 msec. The limit of 0.6 volts can be reached at the upper end of this pulse width range.

However, it is anticipated that the high operating range will be necessary in certain instances. When the high range mode is selected, the integrator controller 174 effectively prolongs the high state TREF square wave by delaying the charging of the integrator capacitor 187 by one clock cycle or 30.5 msec from the beginning of the high state TREF square wave. This effectively shortens the TREF high state pulse width range of 96-146 msec that is integrated back to 66-116 msec, allowing the V_{temp} voltage signal to fall into the 0 - 0.6 volt range that can be doubled in amplifier stage 195, digitized and stored. The programmed range is also stored with the digitized temperature data so that the proper values can be decoded from the telemetered out data.

In order to set the RANGE for proper temperature measurement in a given patient, one or the other range is programmed and the digitized temperature readings are accumulated and telemetered out. If they are in a proper range, then the programmed RANGE is correct. In general, if in the low range mode and if the digital temperature value is a digital word 50 or less, it is necessary to program the high range. And, if in high range mode and the digital word is 200 or more, it is necessary to program to the low range. Alternatively, the range could be automatically switched at these threshold levels.

The rate of charge of integrator capacitor 187 in these ranges to get to the proper voltage range of 0 - 0.6 volts depends on the current I_{ic} . The self calibration of the temperature signal processing channel 164 is necessary to trim the resistor 157 to precisely set the current I_{TEMP} and the current I_{ic} so that a voltage of 0.590 volts is reached on capacitor 187 after a 116 msec integration time. In this mode, the RANGE is programmed to the low range, and the SELF CAL signal is programmed ON. The digital signal processor 162 responds to the SELF CAL ON signal to divide the 32 kHz clock signal provided from digital controller/timer circuit 132 by 6 into a 5.46 kHz square wave signal exhibiting a 50% duty cycle. The digital signal processor substitutes the square wave calibration signal for the TREF signal and applies it to the temperature signal processing channel 164 and to the input of the integrator controller 174. The resistance of resistor 157 is trimmed to adjust integrator current I_{ic} until the voltage 0.590 volts is achieved in 116 msec or an ADC count of 125 is reached.

Turning now to the derivation of the pressure signal V_{prs} , the nominally 5 kHz DCAPS positive and negative square wave of + 2.0 volts is filtered and averaged to derive a voltage signal V_{prs} in the range of 0 - 1.2 volts at the junction of capacitor 182 and resistor 186. The 5 kHz signal component is filtered out by a 4-pole filter including a 250 Hz low pass filter provided by capacitor 165 and resistor 166, an active Butterworth filter comprising 40 Hz low pass filter network 196 and first pressure amplifier stage 197, and a further 1 pole, 250 Hz low pass filter pole comprising capacitor 182 and resistor 186. The low pass filter network 196 comprises the resistors and capacitors 165 -167, 169, 171, 173, 175, 182 and 186 and averages the voltage square wave to create a D.C. voltage proportional to the DCAPS square wave signal duty cycle. The first pressure amplifier stage 197 buffers the filtered pressure-related signal at its output. The filtered output signal is applied to second, inverting, pressure amplifier stage 198 which comprises the amplifier 170 and the programmable gain, switched resistor networks 180 and 181. Amplification and voltage offset of the output signal of amplifier 168 is provided in second pressure amplifier stage 198 by the 2-BIT GAIN, 4-BIT GAIN and 8-bit offset DAC settings.

The variations in the manufacturing tolerances and conditions of the sensor module 20 affects the reference and pickoff capacitance values and the response to

temperature and pressure changes that particularly affect the pressure sensing function.

The gain and offset adjustments are provided to correct for such affects. The offset adjustment is also required to provide for pressure range adjustments so that the pressure range used provides adequate resolution of pressure differences. As
5 mentioned above, the A/D conversion range of the ADC/MUX circuit 142 is limited to 256 digitized values from a voltage range of 1.2 volts. Therefore, it is necessary to compensate for variations in the patient's own blood pressure range as well as prevailing atmospheric pressure primarily related to the altitude that the patient normally is present in. These compensations are included in an offset factor
10 developed at the time of implant.

The offset factor is provided by the 8-bit offset digital to analog converter (DAC) 172 which provides an offset analog voltage dependent on the programmed value of the DAC CNTRL binary coded digital word. The primary function of the DAC 172 is to provide the analog voltage to "zero" the offset in the system in order to
15 keep the pressure signal within the range of the ADC/MUX block 142 (0-1.2 volts). The analog offset voltage is applied to differential pressure amplifier 170 where it is subtracted from the output voltage of the first pressure amplifier 168. The total programmable range of the DAC 172 is 630 mV, between 570 mV to 1,200 mV.

The gain settings for the second pressure amplifier stage 198 can be adjusted
20 by programming values for the 4-BIT GAIN and 2-BIT GAIN binary words stored in the RAM 124 of Figure 1 by the external programmer. The 4-BIT GAIN signal controls the gain of the pressure amplifier stage 198 by setting switched resistors in feedback switched resistor network 180 to the binary coded gain word to provide a gain range that is selectable by the further 2-BIT GAIN signal setting of switched
25 resistor network 181. The gain setting can be varied from 5X - 20X in 1X increments, 10X - 40X in 2X increments and 20X - 80X in 4X increments. The gain ranges and increments are established by the 2-BIT GAIN control signal applied to the series switched resistor network 181.

The first pressure amplifier stage 197 responds to the ratio of Ttemp to the
30 sum of Ttemp and Tprs resulting in a first filtered voltage signal. The second pressure amplifier stage 198 amplifies and inverts the first voltage signal as a function of the offset and gain settings and therefore responds effectively to the ratio of Tprs to

the sum of T_{temp} and T_{prs} , or the duty cycle of T_{prs} . The output signal from amplifier 170 of the second amplifier stage 198 is applied to a further low pass filter stage comprising resistor 186 and capacitor 182 to filter out any remaining component of the about 5 kHz oscillation frequency and/or any noise. The resulting filtered
5 signal is applied as pressure signal V_{prs} to the digital controller/timer circuit 132 of Figure 1.

The resulting V_{prs} and V_{temp} voltage signals are digitized in the ADC/MUX circuit 142 in a manner well known in the art to provide digitized V_{prs} and V_{temp} data values. The digitized V_{prs} and V_{temp} data values are applied on bus 130 to the
10 microcomputer circuit 114 for storage in specified registers in RAM/ROM unit 128. The digitized V_{temp} data value may be employed in processing the digitized data values telemetered out by the external programmer to compensate for the temperature induced affects on the V_{prs} data values. The stored data values may also be correlated to data from the activity sensor block 152 and other sensors, including other
15 lead borne sensors for monitoring blood gases and the patient's EGM as described above.

The capacitive pressure and temperature sensing system described above is intended for implantation in the body of a patient. However, it will be understood that the sensor lead 12 may be implanted as described above through a venous approach
20 but with its proximal connector end coupled through the skin to an external system 100 for ambulatory or bedside use. In addition, the system 100 may be simplified to the extent that the data may be transmitted remotely in real time to an external programmer/transceiver instead of being stored in microcomputer circuit 114. In the latter case, the microcomputer circuit 114 may be eliminated in favor of a more
25 limited, digital discrete logic, programming command memory of types well known in the prior art of pacing.

Variations and modifications to the present invention may be possible given the above disclosure. Although the present invention is described in conjunction with a microprocessor-based architecture, it will be understood that it could be implemented
30 in other technology such as digital logic-based, custom integrated circuit (IC) architecture, if desired.

It will also be understood that the present invention may be implemented in dual-chamber pacemakers, cardioverters, defibrillators and the like. However, all such variations and modifications are intended to be within the scope of the invention claimed by this letters patent.

CLAIMS

1. An implantable capacitive pressure sensor lead for providing signals representative of the magnitude of body fluid pressure at a selected site and ambient operating conditions, including body temperature, at the site comprising:

5 an elongated implantable lead body having proximal and distal end sections and having first and second electrical conductors extending from the proximal end section to the distal end section, said proximal end adapted to be coupled to a biasing signal source, and said distal end section adapted to be implanted in a body position for measuring a varying body fluid pressure; and

10 a pressure sensor module formed in the distal end section of the lead body and coupled to said first and second electrical conductors, the pressure sensor module further comprising:

a module housing attached to said lead body adapted to be positioned in a body cavity and enclosing a hermetically sealed chamber;

15 pressure deformable pickoff capacitor means for varying in capacitance in response to variations in fluid pressure having a first plate formed of a pressure deformable diaphragm of said module housing and a second plate spaced apart therefrom;

20 reference capacitor means having a first plate formed of a non-deformable portion of said module housing and a second plate spaced apart therefrom;

a substrate supported within said module housing for supporting said second plates; and

25 pressure and temperature signal modulating circuit means supported on said substrate within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors.

2. The pressure sensor lead of Claim 1 wherein:

30 said first plate of said pickoff capacitor means is formed of a pressure deformable, planar diaphragm having a first predetermined surface area formed by said module housing of a conductive material with an exterior planar surface and a parallel interior surface within said hermetically sealed chamber, said planar

diaphragm adapted to be deformed in said first predetermined surface area by variations in fluid pressure outside the module housing; and

said first plate of said reference capacitor means is formed by a second predetermined planar surface area of said interior surface spaced apart from and coplanar with said first predetermined surface area and substantially non-deformable by variations in fluid pressure outside the module housing.

3. The pressure sensor lead of Claim 2 further comprising:

means for forming said second plates of said pickoff and reference capacitor means on a first surface of said substrate; and

means for spacing said second plates of said pickoff and reference capacitor means a fixed distance from said first plates of said pickoff and reference capacitor means.

4. The pressure sensor lead of Claim 3 wherein:

said second plates of said pickoff and reference capacitor means further comprise pickoff and reference capacitor platings of a first thickness formed on said first surface of said substrate conforming to said pickoff and reference capacitor plate patterns, respectively; and

said spacing means further comprises:

a plurality of standoffs of a second thickness greater than said first thickness formed on said first surface of said substrate; and

means for urging said standoffs against said interior surface for spacing said second plates of said pickoff and reference capacitor means from said first plates of said pickoff and reference capacitor means by a predetermined gap establishing the same capacitance for both the pickoff and reference capacitors in the absence of deformation of said diaphragm.

5. The pressure sensor lead of Claim 3 wherein said standoffs are formed of standoff platings of said second thickness formed on said first surface of said substrate in areas outside said pickoff and reference capacitor platings and electrically isolated therefrom.

6. The pressure sensor lead of Claim 4 wherein said pressure and temperature signal modulating circuit means is supported on a second surface of said

substrate within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors and to said pickoff and reference capacitor platings.

7. The pressure sensor lead of Claim 1 further comprising:

5 means for supporting said second plates of said pickoff and reference capacitor means on a first surface of said substrate; and

means for spacing said second plates of said pickoff and reference capacitor means a fixed distance from said first plates of said pickoff and reference capacitor means whereby a predetermined gap establishes the same capacitance for both the pickoff and reference capacitors in the absence of deformation of said diaphragm.

10 8. The pressure sensor lead of Claim 7 wherein said pressure and temperature signal modulating circuit means is supported on a second surface of said substrate within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors and to said second plates.

9. The pressure sensor lead of Claim 1 wherein:

15 said module housing is formed of a conductive material having an exterior planar surface and an interior planar surface shaped to form said planar diaphragm having a fixed thickness and perimeter boundary in a planar section thereof to form said first deformable plate of said pickoff capacitor in a pickoff capacitor plate pattern, said interior planar surface extending beyond the boundary of said planar diaphragm to form said first plate of said reference capacitor in a reference capacitor plate pattern
20 adjacent to said first deformable plate.

10. The pressure sensor lead of Claim 9 further comprising:

25 means for forming said second plate of said pickoff capacitor means on a first surface of said substrate, said second plate of said pickoff capacitor means shaped to correspond to said pickoff capacitor plate pattern;

means for forming said second plate of said reference capacitor means on a first surface of said substrate, said second plate of said reference capacitor shaped to correspond to said reference capacitor plate pattern; and

30 means for spacing said second plates of said pickoff and reference capacitor means a fixed distance from said first plates of said pickoff and reference capacitor means.

11. The pressure sensor lead of Claim 10 wherein:

said second plates of said pickoff and reference capacitor means further comprise pickoff and reference capacitor platings of a first thickness formed on said first surface of said substrate conforming to said pickoff and reference capacitor plate patterns, respectively; and

said spacing means further comprises:

a plurality of standoffs of a second thickness greater than said first thickness formed on said first surface of said substrate; and

means for urging said standoffs against said interior surface for spacing said second plates of said pickoff and reference capacitor means from said first plates of said pickoff and reference capacitor means by a predetermined gap establishing the same capacitance for both the pickoff and reference capacitors

12. The pressure sensor lead of Claim 11 wherein said standoffs are formed of standoff platings of said second thickness formed on said first surface of said substrate in areas outside said pickoff and reference capacitor platings and electrically isolated therefrom.

13. The pressure sensor lead of Claim 10 wherein said pressure and temperature signal modulating circuit means is supported on a second surface of said substrate within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors and to said pickoff and reference capacitor platings.

14. The pressure sensor lead of Claim 1 wherein said module housing is fabricated of a conductive metal and further comprising:

insulative body compatible sheath means for electrically isolating said module housing from body fluids and tissue.

15. The pressure sensor lead of Claim 14 wherein said sheath means further comprises an insulative, uniform thickness coating of an adhering body compatible material overlying said diaphragm.

16. The pressure sensor lead of Claim 14 wherein said sheath means further comprises a tubular sheath fitting over said module housing and coupled to said insulative, uniform thickness coating of an adhering body compatible material overlying said diaphragm.

17. The pressure sensor lead of Claim 1 wherein said pressure and temperature signal modulating circuit means further comprises:

means for receiving an externally applied biasing signal on said first and second conductors and for generating charging and discharging currents therefrom which vary in magnitude with ambient temperature;

means for alternately charging and discharging said pickoff and reference capacitor means with said charging and discharging currents; and

timing pulse generating means for generating pickoff and reference timing pulses on one of said electrical conductors, the timing pulses separating the alternate charging time intervals of the pickoff and reference capacitor means.

18. The pressure sensor lead of Claim 17 wherein said timing pulse generating means further comprises:

means for establishing a charge threshold voltage;

means for detecting the charging of said reference capacitor means to said charge threshold voltage and for generating a pickoff timing pulse on said first electrical conductor in response thereto, said pickoff timing pulse having a first predetermined characteristic;

means for detecting the charging of said pickoff capacitor means to said charge threshold voltage and for generating a reference timing pulse in response thereto, said reference timing pulse having a second predetermined characteristic distinguishable from said first predetermined characteristic.

19. An implantable capacitive pressure sensor lead for providing signals representative of the magnitude of body fluid pressure at a selected site and ambient operating conditions, including body temperature, at the site comprising:

an elongated implantable lead body having proximal and distal end sections and having first and second electrical conductors extending from the proximal end section to the distal end section, said proximal end adapted to be coupled to a biasing signal source, and said distal end section adapted to be implanted in a body position for measuring a varying body fluid pressure; and a pressure sensor module formed in the distal end section of the lead body and coupled to said first and second electrical conductors, the pressure sensor module further comprising:

a module housing attached to said lead body adapted to be positioned in a body cavity and enclosing a hermetically sealed chamber;

pressure deformable pickoff capacitor means for varying in capacitance in response to variations in fluid pressure having a first plate formed of a pressure deformable diaphragm of said module housing and a second plate spaced apart therefrom;

reference capacitor means having a first plate formed of a non-deformable portion of said module housing and a second plate spaced apart therefrom; and

pressure and temperature signal modulating circuit means within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors.

20. The pressure sensor lead of Claim 19 wherein said pressure and temperature signal modulating circuit means further comprises:

means for receiving an externally applied biasing signal on said first and second conductors and for generating charging and discharging currents therefrom which vary in magnitude with ambient temperature;

means for alternately charging and discharging said pickoff and reference capacitor means with said charging and discharging currents; and

timing pulse generating means for generating pickoff and reference timing pulses on one of said electrical conductors, the timing pulses separating the alternate charging time intervals of the pickoff and reference capacitor means.

21. The pressure sensor lead of Claim 20 wherein said timing pulse generating means further comprises:

means for establishing a charge threshold voltage;

means for detecting the charging of said reference capacitor means to said charge threshold voltage and for generating a pickoff timing pulse on said first electrical conductor in response thereto, said pickoff timing pulse having a first predetermined characteristic;

means for detecting the charging of said pickoff capacitor means to said charge threshold voltage and for generating a reference timing pulse in response thereto, said

reference timing pulse having a second predetermined characteristic distinguishable from said first predetermined characteristic.

22. The pressure and temperature sensing lead of Claim 21 wherein:
said first predetermined characteristic comprises a first pulse width, pulse
5 amplitude and pulse leading edge slope; and
said second predetermined characteristic comprises a stepped pulse having
leading and trailing steps, said leading step corresponding to said first pulse width,
pulse amplitude and pulse leading edge slope, and said trailing step having a second
pulse amplitude and pulse width.

10 23. A method of fabricating an implantable capacitive pressure sensor lead
for providing signals representative of the magnitude of body fluid pressure at a
selected site and ambient operating conditions, including body temperature, at the site
comprising:

forming an elongated implantable lead body having proximal and distal end
15 sections with first and second electrical conductors extending from the proximal end
section to the distal end section, said proximal end adapted to be coupled to a biasing
signal source, and said distal end section adapted to be implanted in a body position
for measuring a varying body fluid pressure;

covering said first and second electrical conductors with a first body
20 compatible, electrically insulating outer sheath extending from said proximal end
section to said distal end section;

attaching a pressure sensor module to the distal ends of said first and second
electrical conductors at said distal end section, the pressure sensor module further
comprising:

25 a module housing enclosing a hermetically sealed chamber formed of a
conductive material;

pressure deformable pickoff capacitor means for varying in capacitance
in response to variations in fluid pressure having a first plate formed of a
pressure deformable diaphragm of said module housing and a second plate
30 spaced apart therefrom; and

pressure and temperature signal modulating circuit means within said hermetically sealed chamber and electrically coupled to said first and second electrical conductors;

5 covering said sensor module with a second sheath of the same material as said first sheath, the material of said second sheath having a low adherence to the material of said module housing;

providing an opening in said second sheath corresponding to the area of said diaphragm;

10 bonding said second sheath to said first sheath in a fluid tight bond at the junction of said distal end of said lead body with said module housing so that said sheath opening is aligned with said diaphragm;

filling the gap between the perimeter of the opening of the second sheath and the module housing with said further material to decrease the migration of body fluids into the space between the module housing and the second sheath; and

15 applying a further body compatible, electrically insulating material in a uniform thickness layer over said diaphragm in said opening of said second sheath, said further material having a high adherence with the material of said diaphragm in the presence of body fluids and tissue.

20 24. The method of Claim 23 wherein said material of said first and second sheathes is an implantable grade polyurethane and the further body compatible material is an implantable grade silicon rubber.

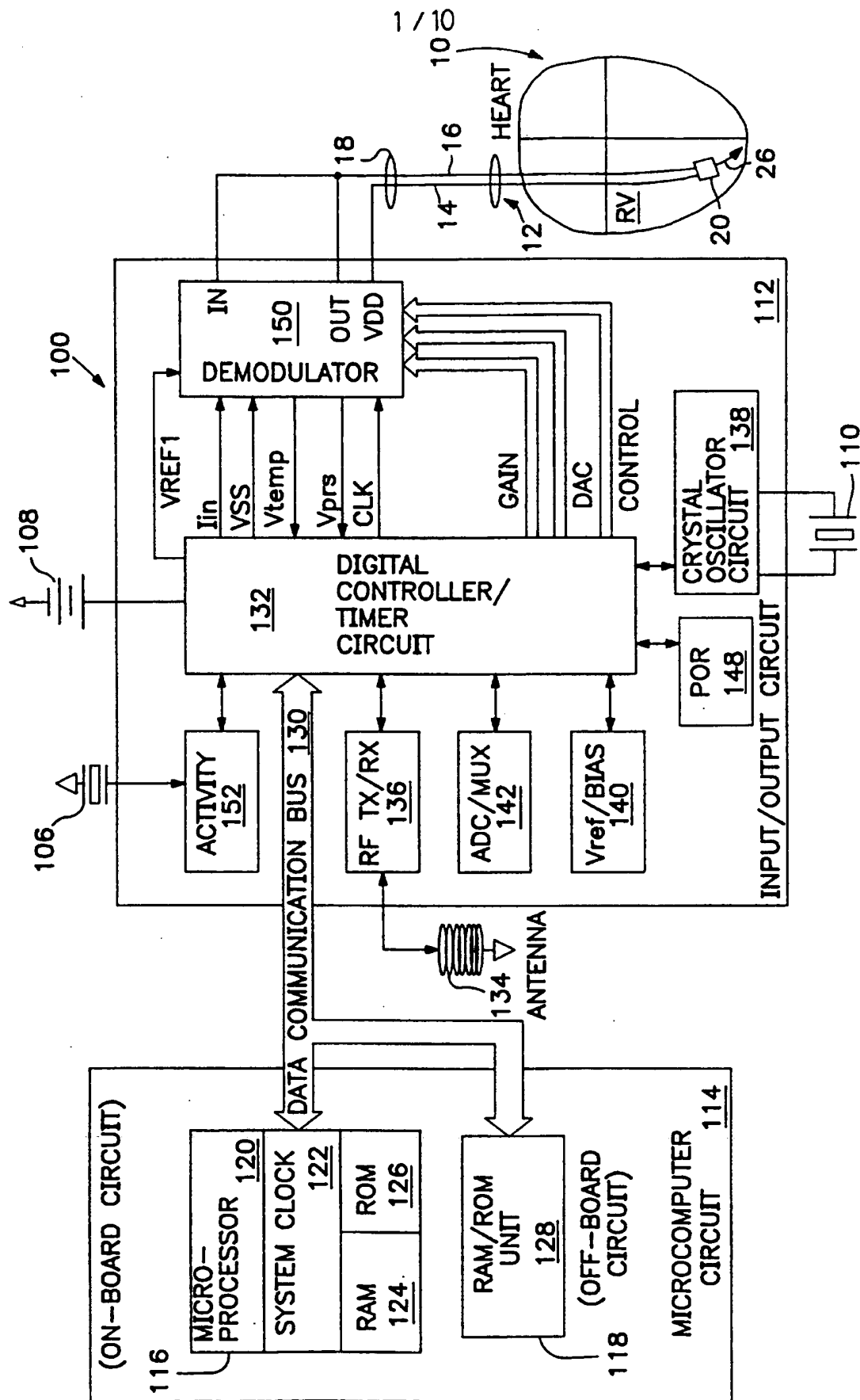


FIG. 1

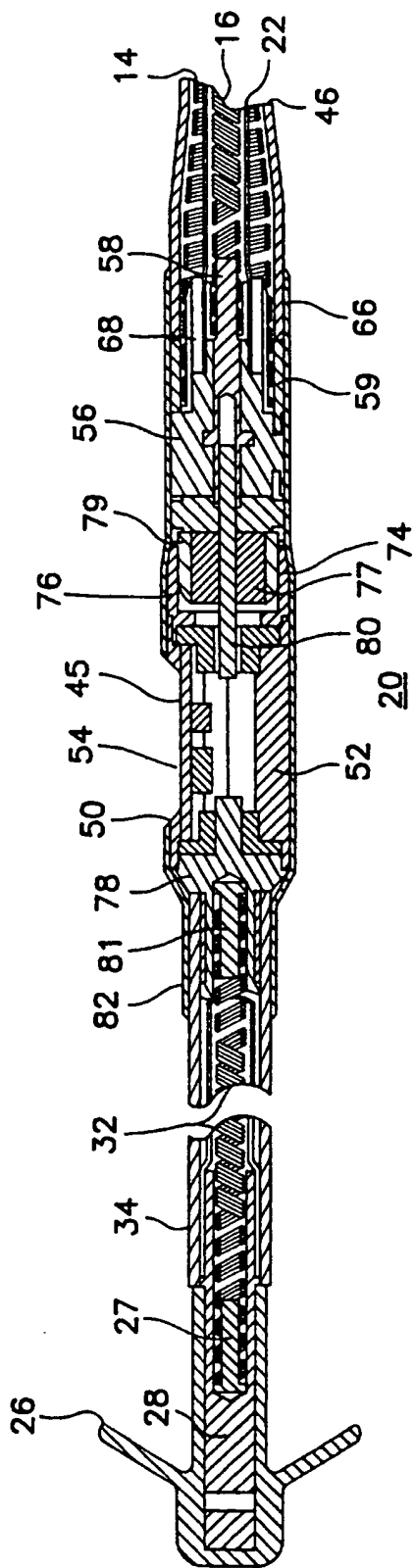


FIG. 2

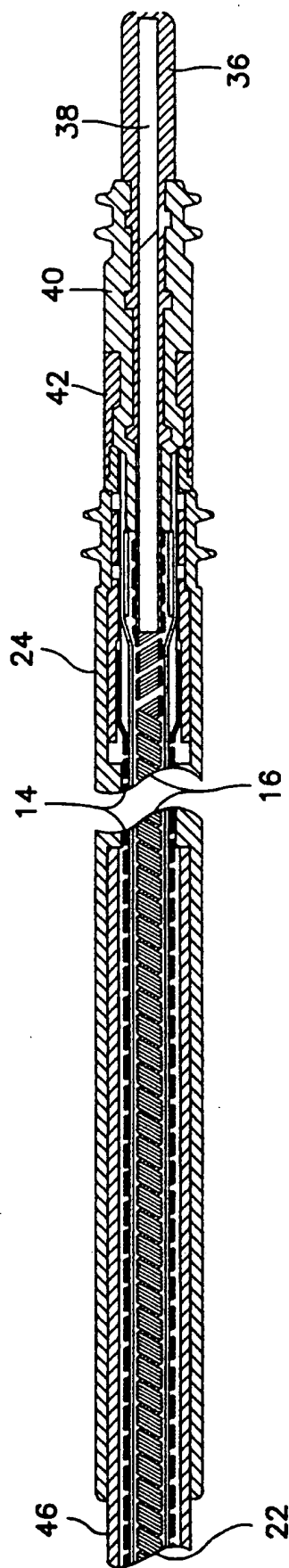


FIG. 3

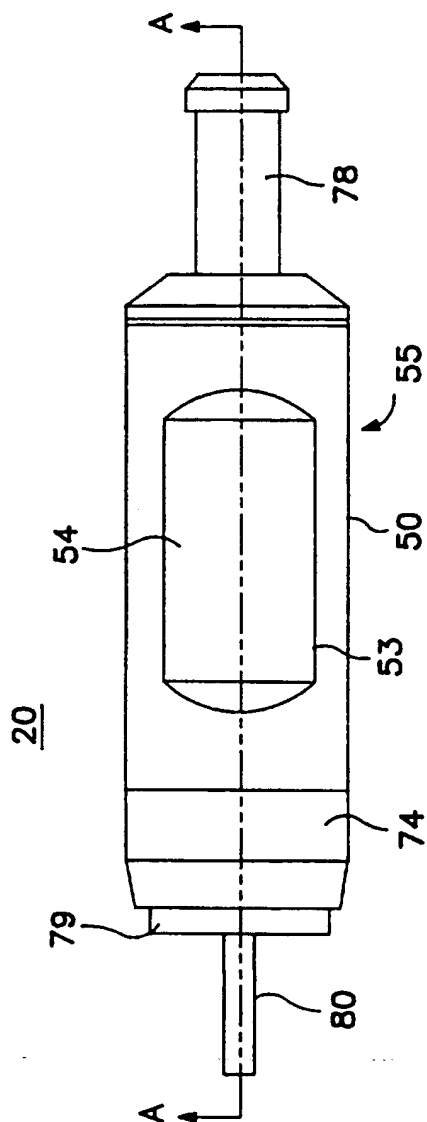


FIG. 4

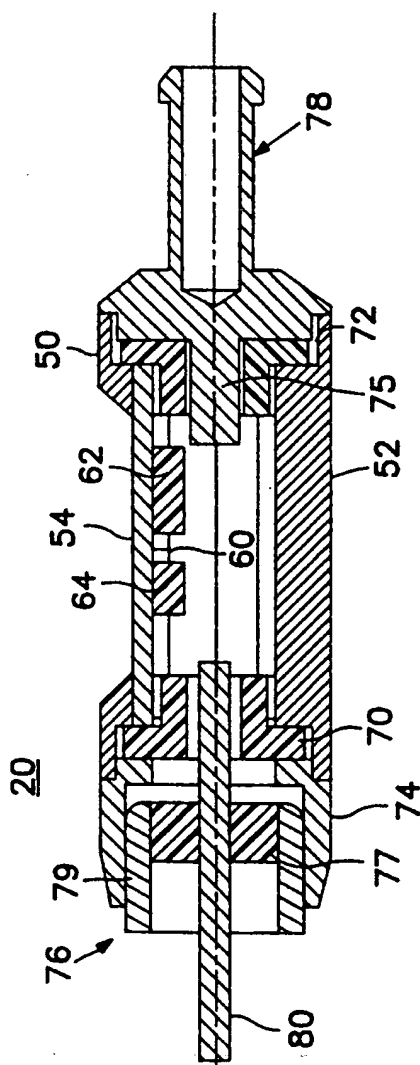
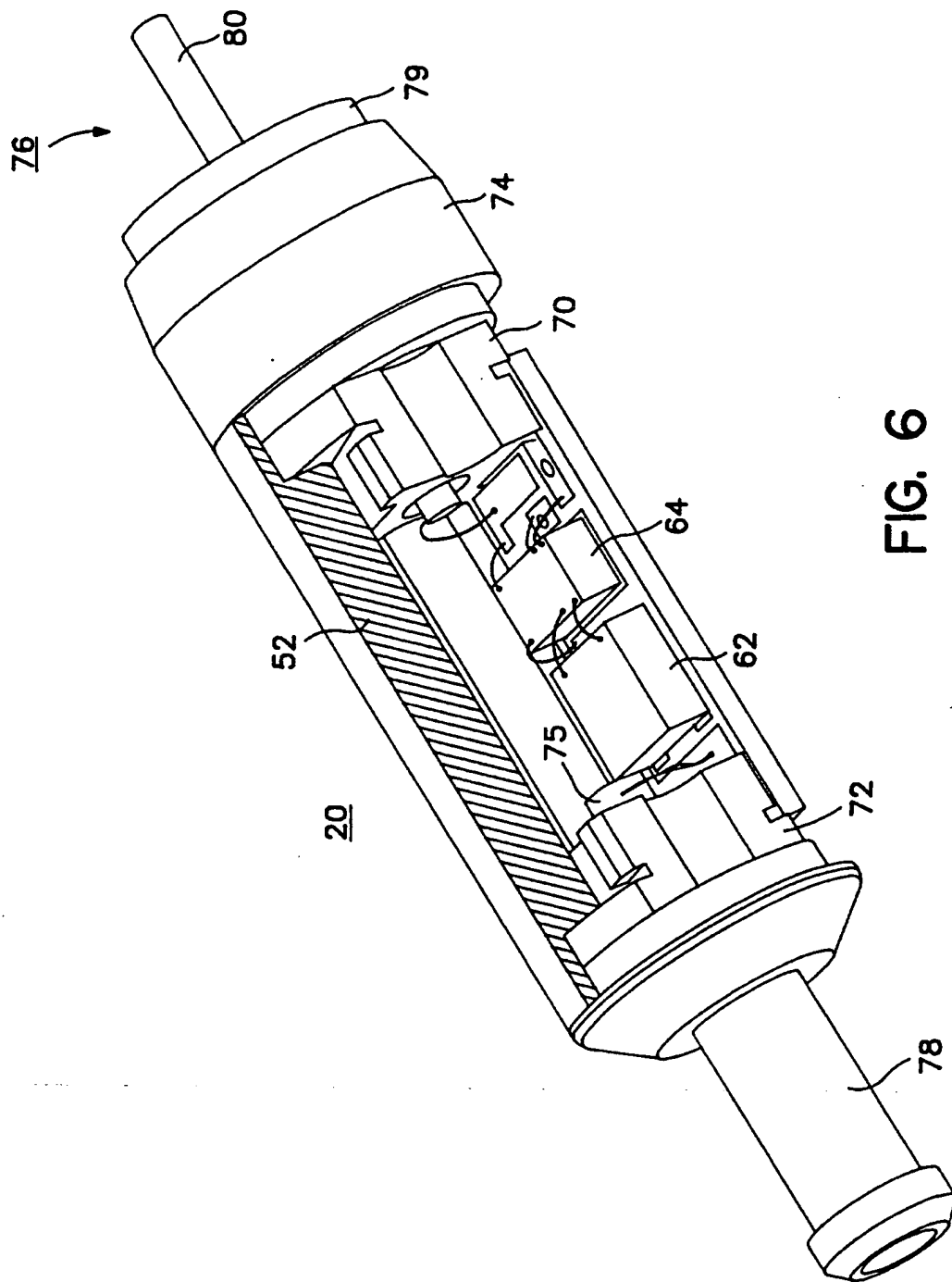


FIG. 5



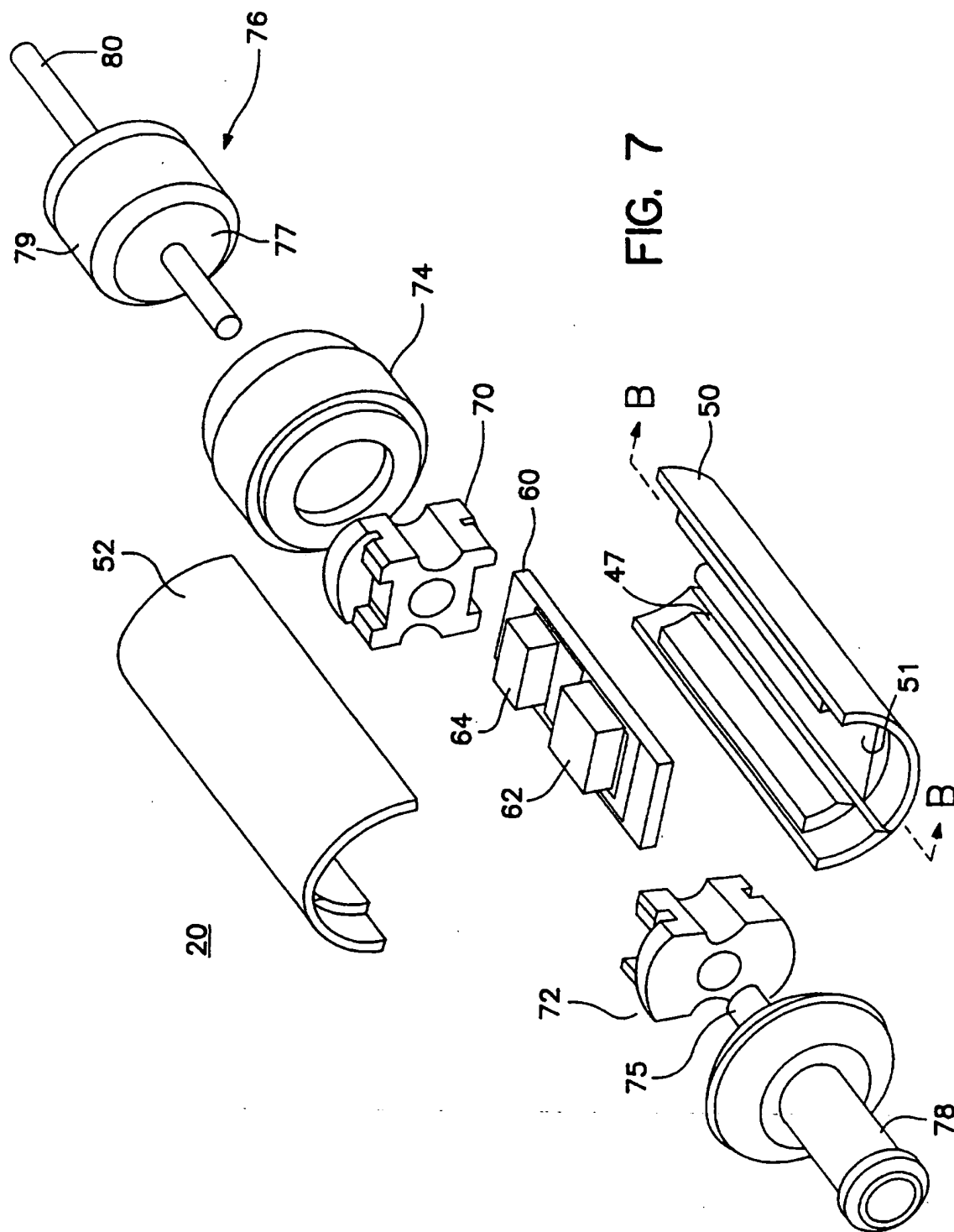


FIG. 7

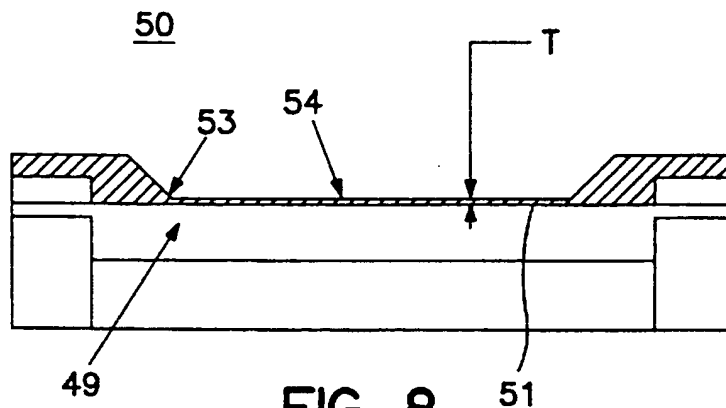


FIG. 8

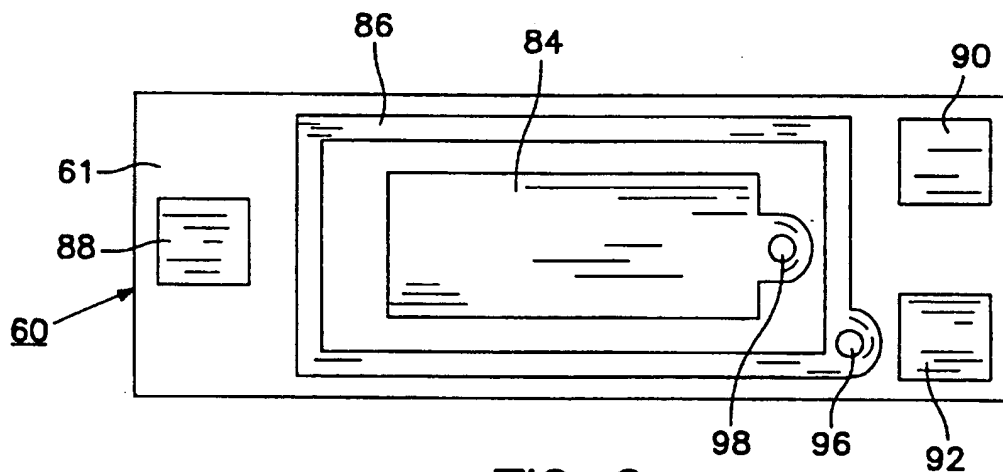


FIG. 9

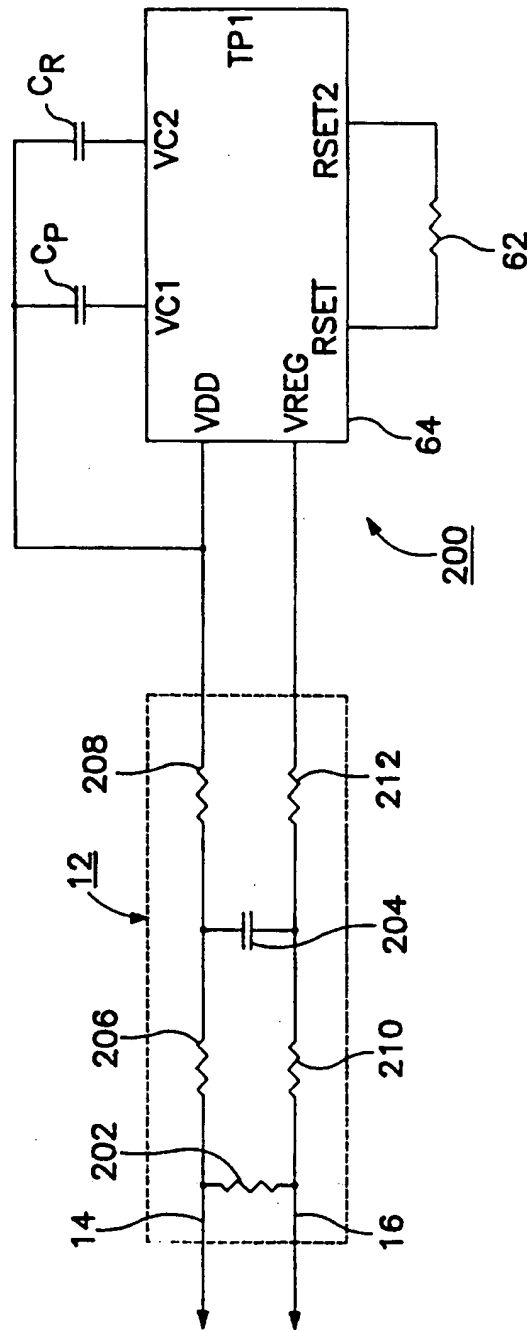


FIG. 10

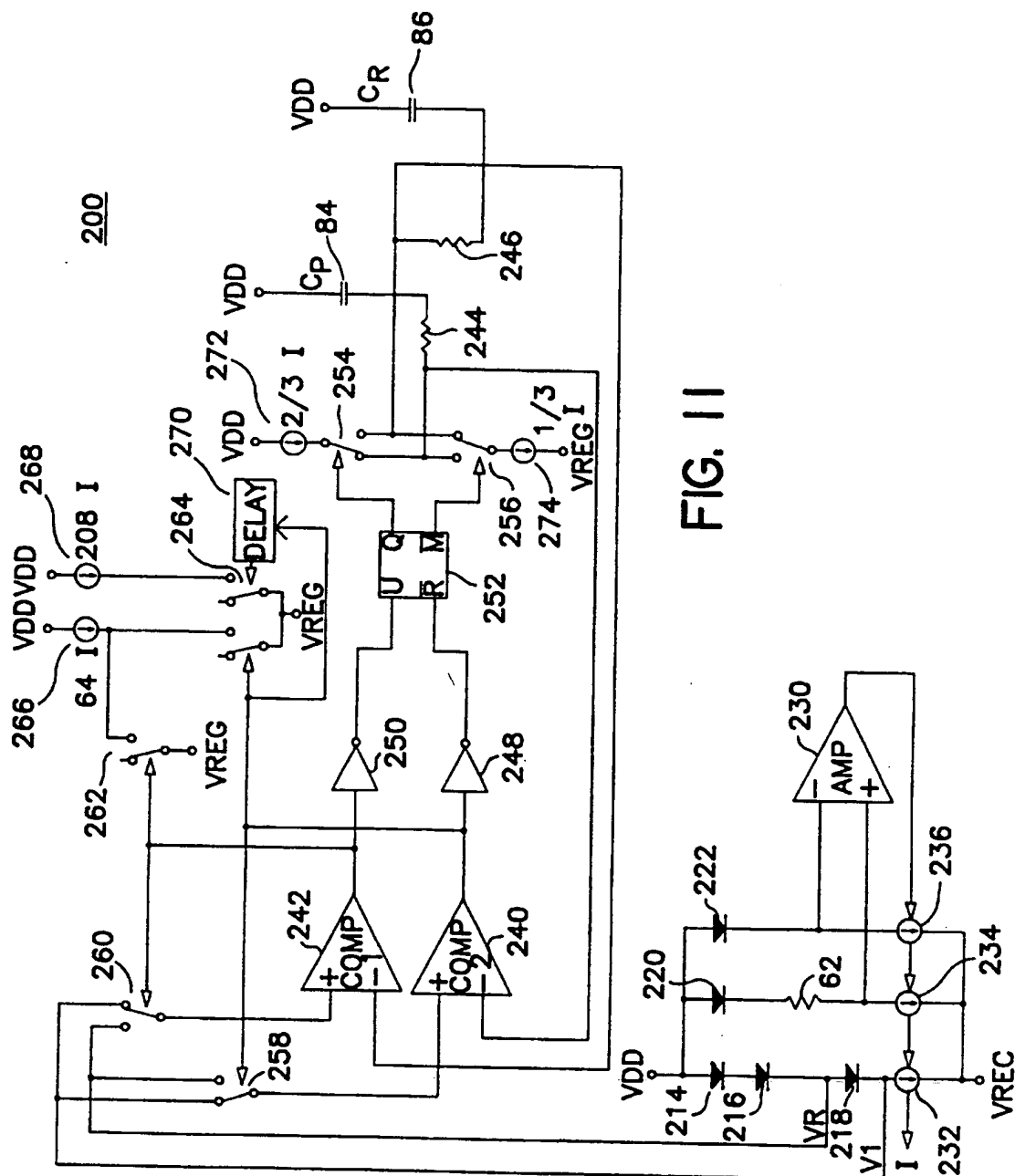


FIG. 11

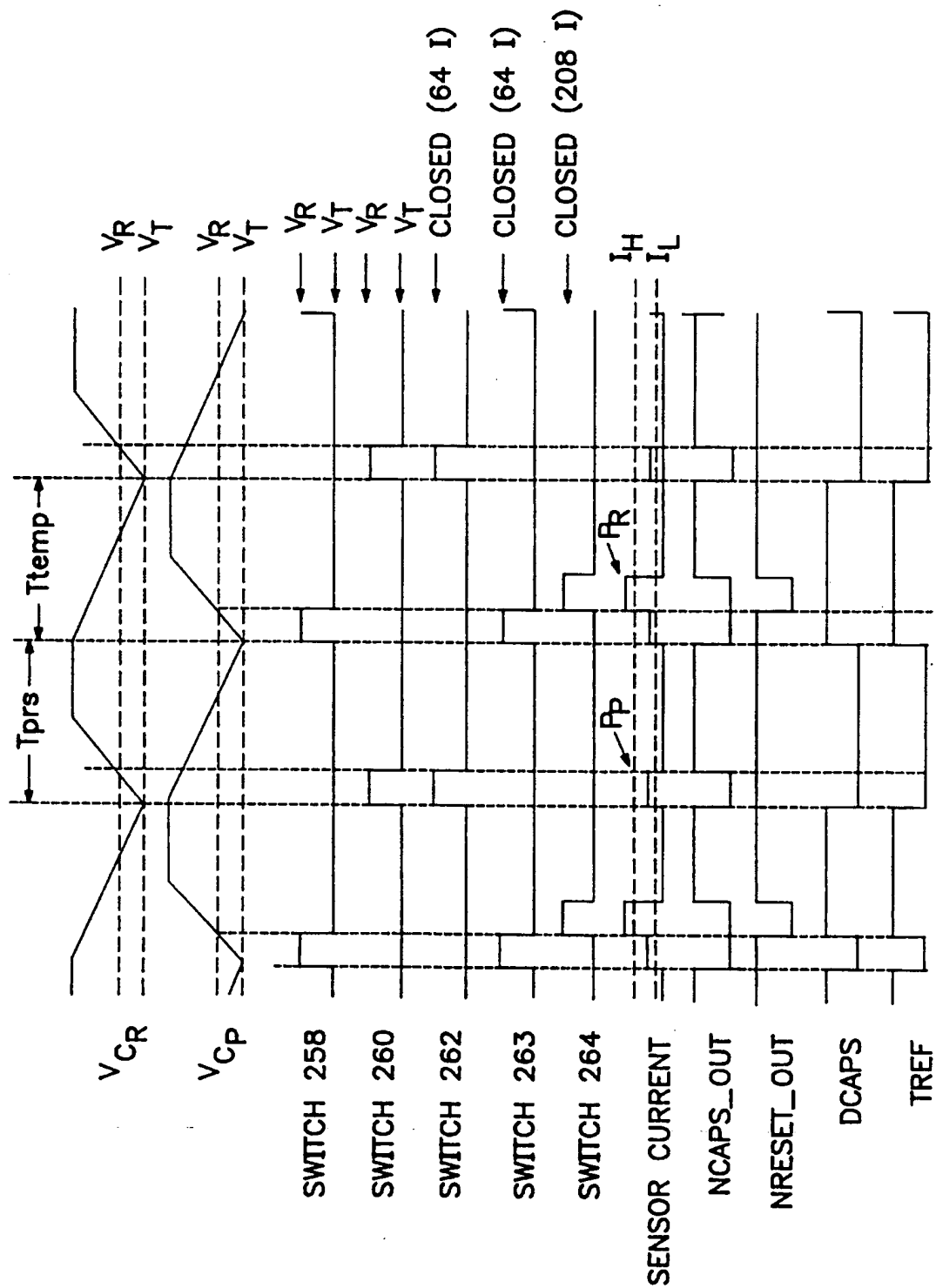


FIG. 12

INTERNATIONAL SEARCH REPORT

International Application No.

PC1/US 96/00975

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC:

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-----------------------|
| X | US,A,4 815 472 (K.D. WISE ET AL.) 28 March 1989 | 1-3,6,8 |
| X | see column 2, line 58 - column 4, line 20 | 9,13-15 |
| X | see column 5, line 1 - column 7, line 22 | 17-21,23 |
| | see column 9, line 21 - column 10, line 14 | |
| | see column 12, line 39 - column 14, line 51 | |
| | --- | |
| | -/-- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

16 July 1996

Date of mailing of the international search report

21.08.96

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+ 31-70) 340-3016

Authorized officer

Rieb, K.D.

INTERNATIONAL SEARCH REPORT

International Application No
PC1/US 96/00975

| C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|--|--|-----------------------|
| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| X | <p>SENSORS AND ACTUATORS, vol. A41, no. 1/3, April 1994, LAUSANNE (CH), pages 198-206, XP000450031 P. WOUTERS ET AL.: "A low power multi-sensor interface for injectable microprocessor-based animal monitoring system" see page 198, right-hand column, paragraph 2 - page 199, left-hand column, paragraph 1 see page 203, right-hand column, paragraph 2 - page 205, right-hand column, paragraph 2</p> | 1-3,19 |
| A | <p>--- US,A,4 237 900 (J.H. SCHULMAN ET AL.) 9 December 1980 see column 3, line 52 - column 4, line 38 see column 7, line 60 - column 8, line 57</p> | 1-3,19 |
| A | <p>--- US,A,5 067 491 (M.S. TAYLOR, II, ET AL.) 26 November 1991 see column 2, line 28 - line 51 see column 3, line 53 - column 4, line 59 -----</p> | 1,19,24 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCI/US 96/00975

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| US-A-4815472 | 28-03-89 | US-A- 4881410 | 21-11-89 |
| | | US-A- 5013396 | 07-05-91 |
| | | US-A- 5113868 | 19-05-92 |
| | | US-A- 5207103 | 04-05-93 |
| ----- | | | |
| US-A-4237900 | 09-12-80 | NONE | |
| ----- | | | |
| US-A-5067491 | 26-11-91 | NONE | |
| ----- | | | |

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.